# EXHIBIT A

### UNITED STATES DISTRICT COURT FOR THE DISTRICT OF NEW JERSEY **CAMDEN VICINAGE**

Document 1451-1

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IN RE: VALSARTAN, LOSARTAN, **IRBESARTAN PRODUCTS** AND

MDL No. 2875

LIABILITY LITIGATION

Honorable Robert B. Kugler, District Court Judge

This Document Relates to All Actions

Honorable Karen Williams, Magistrate Judge

### **EXHIBIT A**

**MANUFACTURER DEFENDANTS'** APPENDIX OF UNPUBLISHED AUTHORITIES

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# Tab 1

2011 WL 5444265 Only the Westlaw citation is currently available. United States District Court, N.D. California.

Tetsuo AKAOSUGI, Hieu Nguyen, on behalf of themselves and others similarly situated, Plaintiffs,

v.

BENIHANA NATIONAL CORP.,
Benihana International, Inc., Benihana
Carlsbad Corp., Benihana Encino Corp.,
Benihana Marina Corp., Benihana Ontario
Corp., Benihana of Puente Hills Corp.,
Benihana Sunrise Corp., Defendants.

No. C 11–01272 WHA.

#### **Attorneys and Law Firms**

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### ORDER GRANTING DEFENDANTS' MOTION TO DISMISS AND VACATING HEARING

WILLIAM ALSUP, District Judge.

#### INTRODUCTION

\*1 In this employment class action, seven defendants move to dismiss all claims against them due to lack of Article III standing. For the following reasons, the motion is **Granted.** 

#### **STATEMENT**

Plaintiffs Tetsuo Akaosugi and Hieu Nguyen worked as managers at Benihana restaurants in San Francisco and Cupertino (First Amd. Compl. ¶¶ 10-11). Plaintiffs commenced this action against Benihana, Inc. on behalf of themselves and others similarly situated for violations of California employment laws, and defendants removed to federal court in March 2011. In September 2011, plaintiffs filed a first defendant and added Benihana National Corporation and seven of its wholly-owned subsidiaries as defendants (Dkt.No.32). Plaintiffs' first amended complaint alleges seven claims for relief: (1) failure to pay overtime; (2) unlawful forfeiture of accrued vacation pay; (3) failure to provide meal periods; (4) failure to provide rest periods; (5) failure to pay wages on termination; (6) failure to provide accurate itemized wage statements; and (7) unfair business practices.

The subsidiaries now move to dismiss all claims, arguing that named plaintiffs lack Article III standing to bring these claims because neither was employed by a Benihana subsidiary. This order follows full briefing.

#### **ANALYSIS**

Lack of Article III standing requires dismissal for lack of subject matter jurisdiction under FRCP 12(b)(1). Simmonds v. Credit Suisse Sec., 638 F.3d 1072, 1087 n. 6 (9th Cir.2011). Article III standing requires the demonstration of three elements: (1) the plaintiff suffered an "injury in fact" that is concrete and particularized and actual or imminent, not conjectural or hypothetical; (2) the injury is fairly traceable to the challenged action of the defendant; and (3) it is likely, as opposed to merely speculative, that the injury will be redressed by a favorable decision. Lujan v. Defenders of Wildlife, 504 U.S. 555, 560-61, 112 S.Ct. 2130, 119 L.Ed.2d 351 (1992). For purposes of ruling on a motion to dismiss for lack of standing, all material allegations of the complaint are accepted as true and the complaint must be construed in favor of the complaining party. Warth v. Seldin, 422 U.S. 490, 501, 95 S.Ct. 2197, 45 L.Ed.2d 343 (1975).

In the class action context, named plaintiffs who represent a class "must allege and show that they *personally* have been injured, not that injury has been suffered by other, unidentified members of the class to which they belong and which they purport to represent." *Gratz v. Bollinger*, 539 U.S. 244, 289, 123 S.Ct. 2411, 156 L.Ed.2d 257 (2003) (emphasis added). If none of the named plaintiffs are able to establish

standing as to each defendant, "none may seek relief on behalf of himself or any other member of the class." *O'Shea v. Littleton*, 414 U.S. 488, 494, 94 S.Ct. 669, 38 L.Ed.2d 674 (1974).

The subsidiaries argue that plaintiffs fail to meet the third element of standing because the injury to named plaintiffs can only be linked to actions of Benihana National, the parent corporation, and *not* to the subsidiaries. The subsidiaries assert that neither named plaintiff was ever employed by one of the seven subsidiaries (Casey Decl. ¶ 2). The Cupertino and San Francisco restaurants where plaintiffs worked were operated by Benihana National (Rose Decl. ¶ 2). Plaintiffs do not allege that they were ever employed by a Benihana subsidiary, but offer several theories why they have standing nonetheless. None is persuasive. Each is considered in turn.

### 1. Standing Must Be Established Before Class Certification.

\*2 Plaintiffs argue that issues regarding standing are best resolved after class certification (Opp.13). This order must disagree. "Standing is a jurisdictional element that must be satisfied prior to class certification." Lee v. State of Oregon, 107 F.3d 1382, 1390 (9th Cir.1997). Plaintiffs cite to Amchem Products, Inc. v. Windsor for the proposition that "class certification issues are dispositive" because their resolution "is logically antecedent to the existence of any Article III issues." 521 U.S. 591, 612, 117 S.Ct. 2231, 138 L.Ed.2d 689 (1997). In Amchem, however, the Supreme Court was presented with challenges to both class certification and jurisdiction. The Court chose to address only the class certification issues, but it did not hold that determination of Article III standing could properly be delayed until after class certification. In the present action, class certification has not yet taken place, but plaintiffs cannot proceed against the subsidiaries if they cannot establish all elements of Article III standing at this stage.

#### 2. A Juridical Link Cannot Bestow Standing.

Plaintiffs argue that they have standing because Benihana National and the subsidiaries are juridically linked. A plaintiff can establish the elements of class certification where "all injuries are the result of a conspiracy or concerted scheme between the defendants," or where "all defendants are juridically related in a manner that suggests a single resolution of the dispute would be expeditious." *LaMar v. H & B Novelty & Loan Co.*, 489 F.2d 461, 466 (9th Cir.1977). In *LaMar*, the court of appeals assumed the presence of standing because the

plaintiffs had not satisfied the class certification requirements of FRCP 23.

All of the decisions plaintiffs cite in their opposition brief, however, involve the class certification process—*not* Article III standing analysis. Since *LaMar*, the court of appeals has only once analyzed a juridical link in the context of Article III, and the court of appeals did not squarely address if finding a juridical link between defendants could establish standing. *See Easter v. Am. W. Fin.*, 381 F.3d 948, 962 (9th Cir.2004) (finding the plaintiffs failed to show a juridical link without reaching the question of if the pleading stage was an appropriate context for this analysis).

Defendants cite to a decision by the undersigned judge holding that juridical link analysis does not apply to issues of standing in the pleading stage. *Siemers v. Wells Fargo & Co.*, No. C 05–04518, 2006 WL 3041090, at \*6 (N.D.Cal. Oct.24, 2006). Indeed, district courts have been hesitant to hold that a juridical link establishes Article III standing. *See Cady v. Anthem Blue Cross Life and Health Ins.*, 583 F.Supp.2d 1102, 1107 (N.D.Cal.2008) (Wilken, J.) (citing to *Siemers* and holding the juridical link analysis inapplicable to determining standing).

In fact, a careful review of all decisions on point revealed that no district court in the Ninth Circuit has found a plaintiff to have established Article III standing based on a juridical link between defendants. *See, e.g., Shin v. Esurance Ins. Co.,* No. C8–5626, 2009 WL 688586, at \*5 (W.D.Wash. Mar.13, 2009) (Leighton, J.) (finding no authority "that binds the Court to treat an alleged juridical link as a trump card in the game of applying the Constitution"). This Court declines to hold otherwise. Accordingly, plaintiffs fail to establish standing on this basis.

#### 3. Alter Ego and Agency Theories Are Inapplicable.

\*3 Plaintiffs argue that they have standing based on alter ego and agency theories, citing to *Bauman v. DaimlerChrysler Corp.*, 644 F.3d 909, 920 (9th Cir.2011). *Bauman* held that the alter ego and agency tests can establish "contacts to support the exercise of personal jurisdiction over a foreign parent company by virtue of its relationship to a subsidiary that has continual operations in the forum." Plaintiffs do not explain how theories pertaining to personal jurisdiction can bestow Article III standing. Even if plaintiffs were able to establish that Benihana National and the subsidiaries are alter egos of one another, they have not presented any authority holding that such a demonstration would establish standing.

Plaintiffs have failed to establish Article III standing because they have not demonstrated that the injury to the named plaintiffs is fairly traceable to the subsidiaries. Accordingly, the motion to dismiss all claims as to the subsidiaries is **Granted.** 

#### **CONCLUSION**

For the foregoing reasons, defendants' motion to dismiss is **Granted.** All claims against the subsidiaries are dismissed. Benihana National remains as a defendant. Plaintiffs may

seek to amend the complaint and will have **twenty-one calendar days** from the date of this order to file a motion, noticed on the normal 35–day track, for leave to file an amended complaint. Plaintiffs must append to their motion a proposed amended complaint that clearly explains how the amendments cure the defects identified herein. The hearing scheduled for November 17 is **Vacated.** 

#### IT IS SO ORDERED.

#### **All Citations**

Not Reported in F.Supp.2d, 2011 WL 5444265

**End of Document** 

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# Tab 2

KeyCite Yellow Flag - Negative Treatment
Distinguished by Agape Flights, Inc. v. Covington Aircraft Engines, Inc.,
E.D.Okla., July 9, 2012

2005 WL 2335369 United States District Court, W.D. Tennessee, Western Division.

AMERICOACH TOURS, INC., individually and as subrogee of Discover Re, Plaintiff,

v.

DETROIT DIESEL CORPORATION, Motor Coach Industries, Inc., and Espar, Inc., Defendants.

> No. 04-2016 B/V, 05-2067 B. | Sept. 23, 2005.

#### **Attorneys and Law Firms**

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ORDER GRANTING DEFENDANT MOTOR COACH INDUSTRIES, INC.'S MOTION TO DISMISS

#### BREEN, J.

\*1 This diversity case arises from the combustion of a tour bus owned by Plaintiff, Americoach Tours, Inc. ("Americoach"). Before the Court is the motion of Defendant Motor Coach Industries, Inc. ("MCI") to dismiss under Rule 12(b)(6), Federal Rules of Civil Procedure, for failure to state a claim upon which relief can be granted filed on February 22, 2005. Americoach filed a response on May 4, 2005. For the

reasons discussed below, the Court GRANTS MCI's motion to dismiss.

#### **BACKGROUND**

On January 25, 2002, a tour bus owned and operated by Americoach caught fire and was completely destroyed. (Consol.Amend.Compl.("Amend.Compl.") ¶ 17.) No injuries or loss of life were sustained as a result of the fire. (Id.) The fire originated in the engine compartment in the left corner of the bus and was caused by a malfunction in the component parts of the heater or by the turbo charger. (Id.¶¶ 23-25.) The heater was manufactured by Defendant Espar, Inc. and designed and installed by MCI. (Id.¶22.) The turbo charger was part of the engine, which was built by Defendant Detroit Diesel Corporation ("DDC") and installed by MCI. (Id.¶23.) MCI is in the business of selling tour buses that it has assembled and outfitted from component parts. (Id.¶¶ 12, 27.)

The bus could not be repaired without incurring more expense than the value of the bus. (Id.¶ 20, 398 S.W.2d 240.)

Americoach alleges that "[t]he fire was caused, either jointly or severally, by a malfunction in the electrical or component parts of the heater designed and tested by MCI and manufactured by Espar and/or the fire was caused by MCI's negligence in outfitting the tour bus as part of its regularly conducted business activity." (Id.¶ 24.) Alternatively, Americoach contends that "[t]he fire was caused, either jointly or severally, by a malfunction in the turbo charger of DDC's engine and/or the fire was caused by MCI's negligence in outfitting the tour bus as part of its regularly conducted business activity." (Id.¶ 25.) Based on these allegations, Americoach brings claims against MCI for negligence, products liability, breach of implied warranty of merchantability, and breach of implied warranty of fitness for a particular purpose. (Id.¶¶ 26-80.) Americoach seeks to recover the value of the bus, \$386,180 and lost profits in the amount of \$163, 238. (Id.¶ 10.)

#### CHOICE OF LAW

Americoach's products liability claim is brought under Tenn.Code Ann. § 29-28-101, et seq., and its claim for breach of implied warranty of merchantability against

MCI is brought under Tenn.Code Ann. § 47-2-314. (Amend.Compl.¶¶ 50, 66.) Americoach assumes, in its response to MCI's motion to dismiss, that Tennessee law applies to all of its claims. MCI states that it also assumes for purposes of its motion to dismiss that Tennessee law applies. (Def.'s Mot. Dismiss ("Def.'s Mot.") at 2.) Because the parties agree to the particular state law application, the court will apply Tennessee law and will not conduct a choice of law analysis sua sponte. See Sneyd v. International Paper Co., Inc., 142 F.Supp.2d 819, 823 (E.D.Mich.2001) (citing GBJ Corp. v. Eastern Ohio Paving Co., 139 F.3d 1080, 1085 (6<sup>th</sup> Cir.1998)); see also Dextrex Chemical Industries, Inc., v. Employers Ins. of Wausau, 746 F.Supp. 1310, 1311 (N.D.Ohio 1990) (applying Michigan substantive law because the parties came to an agreement that Michigan law applied, even though the court had determined, in an earlier sua sponte choice of law analysis, that Wisconsin law should apply).

#### STANDARD OF REVIEW

\*2 "Under the liberal notice pleading rules, a complaint need only put a party on notice of the claim being asserted against it to satisfy the federal rule requirement of stating a claim upon which relief can be granted." Memphis, Tenn. Area Local, Am. Postal Workers' Union, AFL-CIO v. City of Memphis, 361 F.3d 898, 902 (6<sup>th</sup> Cir.2004). When considering a motion to dismiss for failure to state a claim under Fed.R.Civ.P. 12(b)(6), the court must "construe the complaint in the light most favorable to the plaintiff, accept all of the complaint's factual allegations as true and determine whether the plaintiff undoubtedly can prove no set of facts in support of the claims that would entitle relief." Grindstaff v. Green, 133 F.3d 416, 421 (6<sup>th</sup> Cir.1998). "The Federal Rules of Civil Procedure do not require a claimant to set out in detail all the facts upon which [it] bases [its] claim," Conley v. Gibson, 355 U.S. 41, 47, 78 S.Ct. 99, 2 L.Ed.2d 80 (1957). However, "[t]o avoid dismissal under Rule 12(b)(6), a complaint must contain either direct or inferential allegations with respect to all material elements of the claim." Wittstock v. Mark a Van Sile, Inc., 330 F.3d 889, 902 (6<sup>th</sup> Cir.2003).

#### ANALYSIS

I. Negligence and Products Liability Claims

MCI argues that Americoach's negligence and products liability claims must be dismissed because the damages

sought by Plaintiff are purely economic. (Def.'s Mem. Supp. at 1.) The economic loss doctrine, adopted by the Tennessee courts, prohibits purchasers of products from recovering purely economic damages under negligence or products liability theories. Ritter v. Custom Chemicides, Inc., 912 S.W.2d 128, 133 (Tenn.1995); see also HDM Flugservice GmbH v. Parker Hannifin Corp., 332 F.3d 1025 (6th Cir.2003). A defective product causes a purely economic loss when the product causes no personal injuries and damages no property other than the "product itself." East River S.S. Corp. v. Transamerica Delaval, Inc., 476 U.S. 858, 870, 106 S.Ct. 2295, 2302, 90 L.Ed.2d 865 (1986). The rationale for the economic loss doctrine is that, in the absence of personal injuries or property damage, a defective product has simply "not performed as expected" and "the buyer's remedy should be governed by the rules of contract, which traditionally protect expectation interests." Ritter, 912 S.W.2d at 133 (quoting Sanco, Inc. v. Ford Motor Co., 579 F.Supp. 893, 897 (D.Ind.1984)).

Americoach seeks to recover for "property damage" for the bus destroyed by the fire and, in addition, for lost profits. (Amend.Compl.¶ 10.) Profits lost as a consequence of defective goods are considered an economic loss. Messer Griesheim Industries, Inc. v. Cyrotech of Kingsport, Inc., 131 S.W.3d 457, 465 (Tenn.Ct.App.2003) (quoting White & Summers, *Uniform Commercial Code*, § 11-4 (2<sup>nd</sup> Ed.1980)). The issue before the Court, therefore, is whether the loss of the bus is properly characterized as an economic loss, or conversely, as damage to "other property" for which recovery in tort is permissible. East River S.S. Corp., 476 U.S. at 867-70. Americoach argues that a component part of the bus, the heater, was the defective "product itself" and, therefore, the destruction of all other parts of the bus constitutes damage to "other property." (Pl.'s Resp. at 4.) In particular, Plaintiff maintains that "a malfunction in the electrical or mechanical components of the heater" caused the fire and that "when MCI assisted in the design of the heater it installed in the tour bus, that heater was released in the chain of commerce and became the product itself." (Amend. Compl. ¶ 25 and Pl.'s Resp. at 4.) Based on this argument, Plaintiff asserts that the loss of the bus is recoverable non-economic damage as it was caused by the heater, the product itself, to Plaintiff's other property.

\*3 The Tennessee courts have rejected Plaintiff's argument. In *Tennessee Farmers Mut. Ins. Co. v. Ford Motor Co.*, the plaintiff insurance company, as subrogee of a car owner, sued Ford Motor Company because a defect in the steering column of the owner's car caused the car to

combust spontaneously. Tennessee Farmers Mut. Ins. Co. v. Ford Motor Co., No. W2001-00046-COA-R3-CV, 2002 WL 1332492, at \*1 (Tenn.Ct.App.2002). The insurance company argued that the destruction of the car was property damage, not purely economic loss, because the "fires were caused by a malfunction of only one component part." Id. at \*5. The court disagreed and held that the entire vehicle, "destroyed by the spontaneous combustion of a component part, constituted the 'product itself' for the purpose of determining whether the insured suffered only economic loss." Id. at \*6. In reaching its conclusion, the Tennessee court adopted the reasoning of the United States Supreme Court in East River S.S. Corp., applying the economic loss doctrine to an admiralty action, that "integrated packages," rather than separate component parts, are the "product itself." East River S.S. Corp., 476 U.S. at 867 (holding that an entire turbine engine, rather than the solely the defective turbine, is the 'product itself'). In the instant case, MCI, like Ford in Tennessee Farmers, assembled the bus from component parts, and the entire bus, like the car in *Tennessee Farmers*, was therefore the "product itself."<sup>2</sup>

2 The Court notes only one case applying Tennessee law which has reached a different conclusion regarding the characterization of property damage for purposes of the economic loss doctrine. See Corporate Air Fleet of Tennessee, Inc. v. Gates Learjet, Inc., 589 F.Supp. 1076 (M.D.Tenn.1984). In Corporate Air Fleet, the U.S. District Court for the Middle District of Tennessee, applying Tennessee law in a diversity action, considered whether a plaintiff Learjet owner could maintain an action in strict liability against the manufacturer for repairs to the jet after the jet crashed upon landing. After noting that this issue was one of first impression in Tennessee, the court concluded that "[a]n action is one in tort, not contract, when it is established that there was an accident, caused by a defective product, that is unreasonably dangerous to the user or to his property. In this regard, the damage to the product itself satisfies the "physical harm" to the ultimate user or consumer's property." Id. at 1084. Based on this reasoning, the court permitted plaintiff to recover for damages for repairs to the aircraft in strict liability despite recognizing that the only damage suffered by the plaintiff was to the defective product itself. Id. Subsequent decisions by Tennessee courts have not adopted the court's interpretation of Tennessee law. See Tennessee Farmers, 2002 WL 1332492, at \*1 (rejecting recovery in tort where vehicle spontaneously ignited but caused no personal injury or damage to property other than damage to the vehicle itself).; see also Messer Grieshem Industries, Inc., 131 S.W.3d at 466

(adopting the Supreme Court's holding in *Saratoga Fishing* and allowing recovery in tort for damages caused by contaminated feedgas to "other property" ruined as a result of contact with the defective product after it was placed into the stream of commerce as the "product itself").

Rather than characterizing the heater as a defective component part of the bus, Americoach asserts that a "malfunction in the electrical or component parts of the heater" is to blame for the damage to the bus. (Amend.Compl.¶ 24.) Building on this logic, Americoach further reasons that MCI's role in designing the heater equates with the release by MCI of the heater into the stream of commerce as the product itself, not as a component part of the tour bus. (Pl.'s Resp. at 4.) The Court first rejects the assertion that the definition of an integrated package depends on a matter of degree. In East River, a shipbuilder contracted with a turbine manufacturer to design, manufacture and supervise the installation of turbines on four oil-transporting supertankers constructed by the shipbuilder. After completion, the shipbuilder chartered each of the four ships to the petitioners in the case. When the ships were put into service, component parts of the turbines on all four tankers malfunctioned causing damage to the turbine engines. Petitioners argued that recovery in tort for damage to the turbine engine was permissible because the component parts of the turbine which malfunctioned constituted distinct products apart from the damaged engines. The Court rejected this argument, reasoning that "[s]ince all but the very simplest of machines have component parts, [a contrary] holding would require a finding of 'property damage' in virtually every case where a product damages itself. Such a holding would eliminate the distinction between warranty and strict liability." East River S.S. Corp., 476 U.S. at 867 (quoting Northern Power & Engineering Corp. v. Caterpillar Tractor Co., 623 P.2d 324, 330 (Alaska 1981)). Under East River, as followed by Tennessee courts, the lynchpin for defining the "product itself" is not whether the defective item is a component of the product, or, as Americoach argues, a component of a component of the product, but whether the item is part of an integrated package. In the instant case, all electrical or mechanical components of the heater were "supplied ... as part of an integrated package ... properly regarded as a single unit." East River, 476 U.S. at 867. As such, any damage those parts caused to the tour bus is properly considered economic loss.

\*4 The Court also disagrees with Americoach's contention that MCI's role in designing the heater equates with the

release by MCI of the heater into the stream commerce as the product itself. (Pl.'s Resp. at 4.) The Supreme Court has held that "[w]hen a manufacturer places an item in the stream of commerce by selling it to an Initial User, that item is the 'product itself." 'Saratoga Fishing Co. v. J.M. Martinac & Co., 520 U.S. 875, 879, 117 S.Ct. 1783, 138 L.Ed.2d 76 (1997) (holding that an entire ship, rather than its defective hydraulic system, is the product itself) (emphasis added). While it did have a role in the creation of the heater, MCI sold the heater to an initial user as a component part of the tour bus. As such, the tour bus, an integrated package of component parts, rather than the heater, is the product itself.

The Plaintiff next argues that, even if it cannot recoup the loss of the entire bus under negligence or products liability theories, it can recover under those theories for equipment that Americoach "added and replaced" after acquiring the bus. (Pl.'s Resp. at 2.) In support of its position, Americoach relies on Saratoga Fishing Co. v. J.M. Martinac & Co., 520 U.S. 875, 879, 117 S.Ct. 1783, 138 L.Ed.2d 76 (1997). In Saratoga Fishing the United States Supreme Court held that "equipment added to a product after the manufacturer (or distributor selling in the initial distribution chain) has sold the product to an initial user is not part of the product that itself caused physical harm; rather, ... it is 'other property." ' Id. at 884-85. The economic loss doctrine does not preclude recovery in tort for physical damage that a defective product causes to "other property." Id. at 884-85. Thus, in Saratoga Fishing, while the owner of a fishing vessel destroyed as a result of a defective hydraulic system could not maintain an action in tort for the loss of the vessel, the owner could recover in tort for the loss of the skiff, seine net and various spare parts added to the vessel by a user after an initial sale by the manufacturer. Id.; see also Nicor Supply Ships Assoc. v. General Motors Corp., 876 F.2d 501 (5<sup>th</sup> Cir.1989) (holding that a ship charterer, who adds expensive seismic equipment to the ship, may recover for loss of that added equipment in fire caused by a defective engine). The Court reasoned that while parties can contract for appropriate sharing of risk through warranty contracts when a product is introduced into commerce, it is not ordinary business practice for resellers of products to offer warranties. Id. While Plaintiff supports its claims for parts added and replaced in the same argument, we must address them separately.

According to Americoach, all additions it has made to the bus since acquiring it are "other property" and not the "product itself." (Pl.'s Resp. at 4.) While *Saratoga Fishing* may be in accord with Americoach's assertion, Plaintiff's Complaint

seeks damages only for the destroyed bus and for lost profits and fails to specifically allege any losses resulting from equipment added to the bus after the initial sale by MCI.<sup>3</sup> (Amend.Compl.¶ 10.) Consequently, the Court finds that the Complaint fails to state a claim for recovery of any property "added" to the bus by Americoach, or another user, after the initial sale by MCI.

Paragraph 10 of the Amended Complaint, which summarizes Americoach's monetary claims, states, in relevant part:

[Americoach] sues the Defendants for the property damage of a destroyed tour bus in the amount of \$386,180.00, plus lost profits of \$163,238.00, prejudgment interest and other consequential damages associated with the loss.

\*5 Americoach also submits that any replacement parts it has installed since acquiring the bus should be considered "other property." (Pl.'s Resp. at 4.) As a preliminary matter, Americoach's Complaint fails to allege that any parts were replaced. Further, Americoach's cited authority, Saratoga Fishing, does not explicitly address the characterization of replacement parts for purposes of the economic loss doctrine. See Saratoga Fishing Co., 520 U.S. at 877 (noting that the case considers only "extra equipment ... added by the initial user after the first sale and then resold as part of the [product itself] when [it] is later resold to a subsequent user"). The leading case on the application of the economic loss doctrine to replacement parts installed in a product is Sea-Land Service, Inc. v. General Elec. Co., 134 F.3d 149 (3rd Cir.1998), also decided under admiralty law. To determine whether replacement parts installed in a product constitute other property, the Third Circuit applied the "object of the bargain" test, and looked to the object purchased or bargained for by the Plaintiff. 5 Id. at 153; see also Shipco 2295, Inc. v. Avondale Shipyards, Inc., 825 F.2d 925, 928 (5th Cir.1987). The court reasoned that

However, Americoach's Response to Defendant's Motion to Dismiss does claim that Americoach replaced:

much of the equipment within the original tour bus, including the following: applicator valve, fuse to the transmission selector, both tag oil seals, radiator fan drive "U" joint, transmission connections, instruments within panel lights, PA mike, tires, park brake knob, low-beam headlights, ball joints, wheel seals, rotors, seat[] belts, steering wheel covers, alternator, regulator board, hub plug, hub caps, a/

c expansion valve, a/c dryer, compressor, a/c high pressure hose, power steering, strainer, tag tire, and alternator.

(Pl.'s Resp. at 5.)

In Sea-Land, the Third Circuit noted that the object of the bargain test was consistent with the holding in Saratoga Fishing because the test maintains the distinction the Supreme Court drew between components added to a product by a manufacturer before a product's sale to an initial user and those added by a subsequent user to the manufactured product. CompareSea-Land, 134 F.3d at 153, with Saratoga Fishing, 520 U.S. at 1788.

[t]he law is clear that if a commercial party purchases all of the components at one time, regardless of who assembles them, they are integrated into one product. Since all commercial parties are aware that replacement parts will be necessary, the integrated product should encompass those replacement parts when they are installed in the [product].

Sea-Land, 134 F.3d at 154 (internal quotations omitted); see also Agrotors, Inc. v. Bell Helicopter Textron, Inc., 2004 WL 2039954 (E.D.Pa. Sept.9, 2004) (holding that any replacement part becomes part of the pre-existing "product"); Exxon Shipping Co. v. Pacific Resources, Inc., 835 F.Supp. 1195, 1201 (D.Hawai'i 1993) ("An integrated product may have any number of components replaced with spare parts in the ordinary course of events. To hold that these parts are "other property" would lead to absurd results"). Thus, replacement parts, "purchased to be installed and integrated with the [product]" are components of that product; "they have no use to [the Plaintiff] otherwise." Sea-Land, 134 F.3d at 154.

In the instant case, an initial purchaser<sup>6</sup> bargained with MCI for a fully-functioning tour bus. A natural part of that bargain was the awareness that the bus contained components that must be replaced within its lifetime. *Sea-Land*, 134 F.3d. at 154. When Americoach acquired the bus, the product it bargained for was the same: a fully functioning tour bus, but with the knowledge that certain parts would have to be replaced over time. *Id.* Because the replacement parts are component parts to the bus, even when procured in separate transactions, they form part of the integrated whole. Persuaded by the Third Circuit's decision in *Sea-Land*, the Court holds that any equipment Americoach purchased to replace equipment on the bus became integrated into the "product itself" when the equipment was installed.

The initial purchaser of the bus at issue from MCI was identified in Defendant's Motion to Dismiss as El Expreso Bus Co. of Houston, TX. (Def.'s Mot. at 3.)

II. Americoach's Claims for Breach of Implied Warranty of Merchantability and Breach of Implied Warranty of Fitness for a Particular Purpose

\*6 MCI contends that Americoach's claims for breach of implied warranty of merchantability and breach of implied warranty of fitness for a particular purpose must be dismissed because MCI was not in privity with the Plaintiff. (Def.'s Mem. in Supp. at 3.) In response, Americoach contends that lack of privity between it and MCI does not prevent recovery on its breach of implied warranty claims because the bus was "unreasonably dangerous." (Pl.'s Resp. at 5.)

The economic loss doctrine provides that 'in a contract for the sale of goods where the only damages alleged come under the heading of economic losses, the rights and obligations of the buyer and seller are governed exclusively by contract.' Consequently, a plaintiff may not maintain a claim for purely economic losses absent contractual privity with the party charged with responsibility for those losses.

Messer Griesheim Industries, Inc., 131 S.W.3d at 463 (Tenn.Ct.App.2003) (citing Trinity Industries v. McKinnon Bridge Co., 77 S.W.3d 159 (Tenn.Ct.App.2001)). Accordingly, "Tennessee law does not allow recovery of economic losses under a breach of warranty theory absent privity ..." Id. at 473.

The Complaint does not allege privity between Americoach and MCI. Indeed, MCI claims, and Americoach does not dispute, that MCI originally sold the bus in question to "El Expreso Bus Co." of Houston, TX. (Def.'s Mem. in Supp. at 3.) Americoach does not contend that MCI sold the bus to Americoach or that El Expreso Bus Co. and Americoach are related entities. Thus, Americoach and MCI were not in privity and absent some exception, Plaintiff could not recover on its breach of implied warranty claims.

However, Americoach argues that a breach of implied warranty claim for economic loss does not require privity between the parties when the product that is the basis of the law suit is unreasonably dangerous. (Pl.'s Resp at 5.) In support of its position, Americoach asserts that "in Tennessee, privity of contract between the parties is essential to establish a claim for implied warranty unless the product is 'in a defective condition unreasonably dangerous to the user or

to his property.' *Leach v. Wiles*, 58 Tenn.App. 286, 204 (1968)." (Pl.'s Resp. at 5.)

For the purpose of analyzing Americoach's argument, the court has assumed that a bus which spontaneously combusts is an unreasonably dangerous product.

The Plaintiff's quotation from *Leach v. Wiles*, 58 Tenn.App. 286, 429 S.W.2d 823 (Tenn.App.1968) is incomplete. The quoted sentence from *Leach* in its entirety is as follows:

As we understand it, our Supreme Court has gone no further than to hold that in the absence of contractual privity, liability can be imposed upon the manufacturer for breach of implied warranty when 'one sells any product in a defective condition unreasonably dangerous to the user or to his property' as provided in 2 RESTATEMENT (Second) Torts, sec. 402A (1965).

Leach, 429 S.W.2d at 832. Section 402A of the Second Restatement of Torts states that "[o]ne who sells any product in a defective condition unreasonably dangerous to the user or consumer or to his property is subject to liability for physical harm thereby caused to the ultimate user or consumer or to his property ..." Restatement (Second) of Torts § 402A (1965). Reading Leach and the Second Restatement of Torts together, it is clear that the sentence Americoach cites from Leach does not stand for the rule that privity is not required to bring a claim for breach of implied warranty if the product is unreasonably dangerous. Rather, the quoted sentence in Leach states that privity is not required to bring an action for breach of implied warranty when an unreasonably dangerous product has caused property damage or personal injury.<sup>8</sup>

The requirement of personal injury or property damage was codified by the Tennessee legislature in 1972, four years after *Leach* was decided, in what is now Tenn.Code Ann. § 29-34-104, which states:

In all causes of action for personal injury or property damage brought on account of negligence, strict liability or breach of warranty, including actions brought under the provisions of the Uniform Commercial Code, privity shall not be a requirement to maintain such action.

\*7 In support of this interpretation, this Court notes that, in reaching its conclusion, the *Leach* court relied upon the reasoning of *Olney v. Beaman Bottling Co.*, 220 Tenn. 459, 418 S.W.2d 430 (Tenn.1967), a decision by the Tennessee Supreme Court. In *Olney*, the Plaintiff sued for physical injuries she suffered after drinking a soft drink which contained large amounts of partially decayed material on

a theory of breach of implied warranty of fitness. *Id.* At issue before the court was whether Olney, a consumer, could recover from the manufacturer in the absence of privity. In affirming the trial court's decision to sustain a demurrer, the Tennessee Supreme Court noted:

We recognize that strict liability exists upon the manufacturer of a product without fault on his part, under the circumstances outlined in Restatement, Second, Torts § 402A (1965) ... This is a development in the law of torts which seems justified where the conditions specified in the Restatement are established by proof. This liability, however, is not liability for breach of warranty as that term has been known and used generally. See Comment M to Restatement, Second, Torts, § 402A (1965). This Court held in Coca-Cola Bottling Works v. Sullivan, 178 Tenn. 405, 158 S.W.2d 721, 171 A.L.R. 1200 (1942), and in earlier cases, that there is no implied warranty where there is no privity of contract ... To the extent of this holding, Sullivan and its predecessor are still good law and have not been disturbed by subsequent cases in this jurisdiction.

Id. at 431 (emphasis added). Because the plaintiff's declaration failed to allege that the product was in a defective and unreasonably dangerous condition at the time it left the hands of the manufacturer, the court concluded that the plaintiff had failed to state a cause of action under the Restatement. Only after reaching this conclusion did the court consider whether privity existed between the plaintiff and defendant manufacturer. On the basis of this mode of analysis, the *Leach* court concluded that "we must necessarily reach the conclusion that the rule requiring privity of contract between the parties as an essential element of implied warranty still exists in Tennessee, except in cases where the product involved is 'in a defective condition unreasonably dangerous to the user or to his property." Leach, at 303, 429 S.W.2d 823. However, in *Olney*, the additional requirement of the Restatement's application, namely, that the defective product caused "physical harm ... to the ultimate user" was established. Restatement Second Torts § 402A. Thus, had the plaintiff's declaration alleged, in addition to her physical injuries, that the product was in a defective and unreasonably dangerous condition at the time it left the hands of the manufacturer, the conditions specified in the Restatement would have been established by proof, and privity would not have been required.

In contrast, in the instant case, Americoach has not established non-economic damages and thus, the requirement of privity is not excused regardless of whether the product was unreasonably dangerous. See e.g., Ford Motor Co.

v. Lodon, 217 Tenn. 400, 421-22, 398 S.W.2d 240, 250 (Tenn.1966) ("There seems to be no unfairness in holding that a manufacturer who markets a product which is not only defective but unreasonably dangerous should be responsible for any *physical harm which results to person or property*, even though no privity of contract and no negligence can be established.") (emphasis added).

- \*8 The Court has found no opinion in which a Tennessee court has held that in the absence of privity a plaintiff could bring a claim for breach of an implied warranty to recover only economic damages, nor has the Plaintiff cited to any such authority. Consequently, under Tennessee law, as Americoach has no claim against MCI under a breach of implied warranty theory, Plaintiff's claims against the Defendant for breach of MCI's implied warranty of merchantability and for breach of MCI's implied warranty of fitness for a particular purpose must be dismissed.
- While many courts, like those in Tennessee, bar recovery for economic loss on an implied warranty theory absent privity, "[a] growing number of courts now allow

non-privity plaintiffs to recover for direct (and even consequential) economic loss." *See* White & Summers, Uniform Commercial Code 11-5 (4th ed.) (citing cases from courts which require privity as well as those who have abolished the requirement).

#### **CONCLUSION**

For the foregoing reasons, the Court GRANTS Defendant MCI's motion to dismiss Plaintiff's claims against MCI for negligence, products liability, breach of implied warranty of merchantability and breach of implied warranty of fitness for a particular purpose. As such, MCI is DISMISSED as a defendant in the instant action.

IT IS SO ORDERED this 24 day of September, 2005.

#### **All Citations**

Not Reported in F.Supp.2d, 2005 WL 2335369, 59 UCC Rep.Serv.2d 547

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Case 1:19-md-02875-RMB-SAK Document 1451-1 Filed 08/02/21 Page 18 of 322 PageID: 33080

# Tab 3

2020 WL 5105197 Only the Westlaw citation is currently available. **NOT FOR PUBLICATION** 

United States District Court, D. New Jersey.

ATLAS COMMUNICATIONS TECHNOLOGY, INC., Plaintiff,

DXC TECHNOLOGY SERVICES, LLC, and Citibank, N.A., Defendants.

> Case No. 3:19-cv-19033-BRM-DEA | Signed 08/31/2020

#### **Attorneys and Law Firms**

Kathryn V. Hatfield, Stefani C. Schwartz, Weiner Law Group LLP, Parsippany, NJ, for Plaintiff.

Allyson Marie Mckinstry, Rebecca Monck Ricigliano, Crowell & Moring LLP, New York, NY, for Defendants.

#### **OPINION**

Martinotti, District Judge

\*1 Before this Court is Defendant Citibank, N.A.'s ("Citibank" or "Defendant") Motion to Dismiss Plaintiff Atlas Communications Technology, Inc.'s ("Atlas" or "Plaintiff") Amended Complaint. (ECF No. 18.) Atlas opposes the Motion. (ECF No. 24.) Having reviewed the submissions filed in connection with the motions and having declined to hold oral argument pursuant to Federal Rule of Civil Procedure 78(b), for the reasons set forth below and for good cause shown, Citibank's Motion to Dismiss is **GRANTED.** 

#### I. Background

For the purposes of deciding Motions to Dismiss, the Court accepts the factual allegations in the Complaint as true and draws all inferences in the light most favorable to the Plaintiff. See Phillips v. Cty. of Allegheny, 515 F.3d 224, 228 (3d Cir. 2008). Further, the Court also considers any "document integral to or explicitly relied upon in the complaint." In re Burlington Coat Factory Sec. Litig., 114 F.3d 1410, 1426 (3d

Cir. 1997) (quoting *Shaw v. Dig. Equip. Corp.*, 82 F.3d 1194, 1220 (1st Cir. 1996)).

This action stems from an agreement (the "Statement of Work" or "SOW") dated May 15, 2017, between Atlas and DXC technology services ("DXC") in support of Citibank. (ECF No. 16 ¶ 6.) Atlas is a staffing service provider based in Plainsboro, New Jersey, and DCX is a system integration and information services company with its principal place of business in Tysons Corner, Virginia. (*Id.* ¶¶ 3-4.) The SOW was a renewal contract that continued services provided to DXC's predecessor. (*Id.* ¶ 6.) Additionally, the SOW provides that Atlas will supply DXC with qualified on-site technicians to "provide local support in the fulfillment of maintenance and repair activities, IMACs and Projects related to related to in-scope End User Technology products and services at Citibank sites throughout the Country." (*Id.* ¶ 7.)

Pursuant to the SOW, Atlas provided more than fifty consultants to DXC-who directed the consultants' time, attendance, and scope of work for Citibank sites. (Id. ¶ 8.) Atlas provided DXC with monthly invoices and expenses, which were sent to and approved by DXC Account General Manager, Mark Angarola. (Id. ¶¶ 9-10.) In February 2019, DXC notified Atlas that DXC suspected that certain Atlas consultants and DXC employees were engaged in a scheme to defraud DXC. (Id. ¶¶ 11-12.) In response to the allegations, Atlas immediately terminated the consultants and both Atlas and DXC conducted independent investigations. (Id. 12-13.) During the investigation, DXC advised Atlas that Mark Angarola was at the center of the scheme and the terminated Atlas consultants were also involved. (Id. ¶ 14.) According to DXC, Angarola directed the hiring on consultants who he knew personally and had those individuals submit fabricated time sheets and expenses to Atlas for payment by DXC. (Id. ¶ 15.)

Ultimately, DXC determined Atlas had assessed a 10% mark-up on the expenses incurred by its consultants, though Atlas believed this mark-up had been approved by Angarola. (*Id.* ¶ 17.) In response, Atlas offered to reimburse DXC for the 10% mark-up charge dating back to October 2015. (*Id.* ¶ 18.) Concomitantly, Atlas continued to provide DXC with technicians to service the Citibank sites. (*Id.* ¶ 19.) However, contrary to the terms of the SOW, DXC refused to pay Atlas's invoices and has resorted to self-help. (*Id.* ¶¶ 20-21.) Notwithstanding, Atlas continued to render services to DXC based on DXC's representations that payment was

forthcoming. (*Id.*  $\P$  23.) To this day, DXC has not paid Atlas. (*Id.*  $\P$  22.)

\*2 Furthermore, in July and August 2019, Atlas learned that DXC had—without notice or approval from Atlas—offered employment to nearly all of Atlas's employees in knowing violation of their employment agreement. (*Id.* ¶¶ 25-26.) Despite Atlas's requests to cease, DXC has hired more than fifty of Atlas's former employees. (*Id.* ¶ 28.)

On October 16, 2019, Atlas filed a four-count Complaint against DXC and Citibank (ECF No. 1) and on December 5, 2019, Atlas filed a six-count Amended Complaint asserting claims of breach of contract (Counts One and Six), tortious interference with contract (Count Two), unjust enrichment (Count Three), fraudulent inducement (Count Four), and quantum meruit (Count Five). (ECF No. 16.) On January 6, 2020, Citibank filed a Motion to Dismiss the claims against them pursuant to Fed. R. Civ. P. 12(b)(6). (ECF No. 18.) On January 21, 2020, Atlas filed an Opposition to Citibank's Motion to Dismiss. (ECF No. 24.) On January 27, 2020, Citibank filed a Reply to Atlas's Opposition. (ECF No. 26.)

#### II. Legal Standard

In deciding a motion to dismiss pursuant to Federal Rule of Civil Procedure 12(b)(6), a district court is "required to accept as true all factual allegations in the complaint and draw all inferences in the facts alleged in the light most favorable to the [plaintiff]." Phillips v. Cty. of Allegheny, 515 F.3d 224, 228 (3d Cir. 2008). "[A] complaint attacked by a Rule 12(b)(6) motion to dismiss does not need detailed factual allegations." Bell Atlantic Corp. v. Twombly, 550 U.S. 544, 555 (2007) (citations omitted). However, the plaintiff's "obligation to provide the 'grounds' of his 'entitle[ment] to relief' requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action." Id. (citing Papasan v. Allain, 478 U.S. 265, 286 (1986)). A court is "not bound to accept as true a legal conclusion couched as a factual allegation." Papasan, 478 U.S. at 286. Instead, assuming the factual allegations in the complaint are true, those "[f]actual allegations must be enough to raise a right to relief above the speculative level." Twombly, 550 U.S. at 555.

"To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to 'state a claim for relief that is plausible on its face.' " *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (citing *Twombly*, 550 U.S. at 570). "A claim has facial plausibility when the pleaded factual content allows the court to draw the reasonable inference

that the defendant is liable for misconduct alleged." *Id.* This "plausibility standard" requires the complaint allege "more than a sheer possibility that a defendant has acted unlawfully," but it "is not akin to a 'probability requirement.'" *Id.* (quoting *Twombly*, 550 U.S. at 556). "Detailed factual allegations" are not required, but "more than an unadorned, the defendant-harmed-me accusation" must be pled; it must include "factual enhancements" and not just conclusory statements or a recitation of the elements of a cause of action. *Id.* (citing *Twombly*, 550 U.S. at 555, 557).

"Determining whether a complaint states a plausible claim for relief [is] ... a context-specific task that requires the reviewing court to draw on its judicial experience and common sense." *Iqbal*, 556 U.S. at 679. "[W]here the well-pleaded facts do not permit the court to infer more than the mere possibility of misconduct, the complaint has alleged—but it has not 'show[n]'— 'that the pleader is entitled to relief.' " *Id.* at 679 (quoting Fed. R. Civ. P. 8(a)(2)). However, courts are "not compelled to accept 'unsupported conclusions and unwarranted inferences,' " *Baraka v. McGreevey*, 481 F.3d 187, 195 (3d Cir. 2007) (quoting *Schuylkill Energy Res. Inc. v. Pa. Power & Light Co.*, 113 F.3d 405, 417 (3d Cir. 1997)), nor "a legal conclusion couched as a factual allegation." *Papasan*, 478 U.S. at 286.

\*3 While, as a general rule, the court may not consider anything beyond the four corners of the complaint on a motion to dismiss pursuant to Rule 12(b)(6), the Third Circuit has held that "a court may consider certain narrowly defined types of material without converting the motion to dismiss [to one for summary judgment pursuant to Rule 56]." *In re Rockefeller Ctr. Props. Sec. Litig.*, 184 F.3d 280, 287 (3d Cir. 1999). Specifically, courts may consider any "document *integral to or explicitly relied upon* in the complaint." *Burlington Coat Factory*, 114 F.3d at 1426 (quoting *Shaw*, 82 F.3d at 1220).

#### III. Decision

#### A. Breach of Contract

Citibank contends Atlas has failed to state a claim for breach of contract because (1) Atlas has failed to allege sufficient facts to assert a third-party beneficiary claim, (2) the contract expressly prohibits third-party recovery, and (3) Citibank has a valid defense. (ECF No. 8-1 at 11-15.)

Under New Jersey law, <sup>1</sup> to state a claim for breach of contract, a plaintiff must show that (1) a valid contract existed, (2) the defendant failed to perform under the contract, (3) damages flowing therefrom, and (4) the party stating the claim performed its own contractual obligations. *See Frederico v. Home Depot*, 507 F.3d 188, 203 (3d Cir. 2007).

1 Citibank cited authority under New York law because it contends New York law governs the contract between DXC and Citibank. (See ECF No. 18-1 at 11 n.2.) However, asking this Court to apply New York law is a choice of law issue, which is premature at this stage. See Snyder v. Farnam Cos., Inc., 792 F. Supp. 2d 712, 721 (D.N.J. 2011) (postponing a choice of law analysis until after the motion to dismiss stage when there exists a more complete factual record). Nevertheless, this Court must still determine whether Atlas has stated a breach of contract claim. Because Atlas brought this claim under New Jersey law, the Court will, at this stage, apply New Jersey law in examining the sufficiency of Atlas's claims. See id. (applying New Jersey law at the motion to dismiss stage where plaintiffs brought contract claims under New Jersey law).

To state a claim as a third-party beneficiary, a plaintiff must "show that the contract was made for the benefit of that third party within the intent and contemplation of the contracting parties." *Grant v. Coca-Cola Bottling Co. of New York, Inc.*, 780 F. Supp. 246, 248-49 (D.N.J. 1991) (citing *First National State Bank of New Jersey v. Commonwealth Federal Savings and Loan Assoc.*, 610 F.2d 164, 170 (3d Cir. 1980)). "A third-party who merely stands to benefit from a contract is no more than an incidental beneficiary who incurs no contractual right to enforce the contract." *Id.* (citing Restatement (Second) of Contracts § 315 at 477 (1979)). "[T]he intention of the parties to recognize a right of performance in the third party is the critical factor that governs the characterization of the beneficiary." *Berel Co. v. Sencit F/G McKinley Assoc.*, 710 F. Supp. 530, 537 (D.N.J. 1989).

Here, Atlas alleges they are a third-party beneficiary of a written contract between Citibank and DXC. (ECF No. 16 ¶¶ 56-57.) Citibank, however, contends this conclusory statement is insufficient to state a claim for a third-party beneficiary breach of contract claim. The Court agrees. The "critical factor" in determining whether a third party can assert rights as a third-party beneficiary is the intention of the contracting parties. *See Berel*, 710 F. Supp. at 537. Indeed, the "real test" in determining if a party is a third-party beneficiary to a contract is "whether the contracting parties intended that a third party should receive a benefit which might be enforced

in the courts." *Brooklawn v. Brooklawn Housing Corp.*, 11 A.2d 83, 85 (N.J. 1940). Atlas's conclusory allegation is insufficient to demonstrate Citibank and DXC intended for their contract to give Atlas a benefit which might be enforced in the courts. *See Villegas v. Correctional Med. Servs., Inc.*, No. 14-7337, 2016 WL 3708218 (D.N.J. July 12, 2016) (dismissing third-party beneficiary claim where plaintiff had not provided supporting facts "[o]ther than his conclusory allegation that he is an intended third-party beneficiary). As such, Atlas has failed to adequately allege a third-party beneficiary claim.

\*4 Nevertheless, Atlas contends dismissal of their thirdparty beneficiary claim against Citibank is premature at this stage because discovery has yet to take place. (ECF No. 24 at 11-12.) Generally, questions of contract interpretation should not be decided without the benefit of discovery and a full evidentiary record. See Arlandson v. Hartz Mountain Corp., 792 F. Supp. 2d 691, 699 (D.N.J. 2011). However, discovery is only appropriate where there are different interpretations or ambiguities within a contract. See Hofman v. Time Warner Cable, Inc., No. 12-978, 2013 WL 2460121, at \*7 (D.N.J. June 6, 2013). Atlas has not identified an ambiguity or differing interpretation of the contract between Citibank and DXC. Therefore, this Court may appropriately dismiss the third-party beneficiary claim at this stage. Accordingly, Citibank's Motion to Dismiss Count Six of the Amended Complaint is **GRANTED**.

#### **B.** Equitable Claims

Citibank contends Atlas has failed to plead the requisite elements to state its equitable claims for unjust enrichment and quantum meruit. (ECF No. 18-1 at 15-16.) The Court will address each claim in turn.

To state a claim for recovery based on quantum meruit, a plaintiff must establish four elements: (1) the performance of services in good faith; (2) the acceptance of the services by the person to whom they are rendered; (3) an expectation of compensation therefore; and (4) the reasonable value of the services. *Starkey, Kelly, Blaney, & White v. Estate of Nicolaysen*, 796 A.2d 238, 242-43 (N.J. 2002) (citing *Longo v. Shore & Reich, Ltd.*, 25 F.3d 94, 98 (2d Cir. 1994)). The related theory of unjust enrichment involves two essential elements: (1) a plaintiff must demonstrate that a defendant received a benefit; and (2) that retention of that benefit would be unjust. *TBI Unlimited, LLC v. Clearcut Lawn Decisions*,

LLC, No. 12-3355, 2013 WL 1223643, at \*4-5 (D.N.J. Mar. 25, 2013) (citing MK Strategies, LLC v. Ann Taylor Stores Corp., No. 07-2519, 2007 WL 4322796, at \*3 (D.N.J. Dec. 6, 2007)). In order to prove this second element, a plaintiff must show that it expected remuneration from the defendant at the time it performed or conferred a benefit on the defendant. Id. Therefore, both the second element of an unjust enrichment claim and the third element of a quantum meruit claim require a showing of an expectation of compensation or payment from the party against whom relief is sought.

Citibank contends Atlas's equitable claims must fail because Atlas has not alleged it expected payment directly from Citibank. (ECF No. 25 at 11.) The Court agrees. Unjust enrichment and quantum meruit claims require dismissal where a plaintiff fails to allege it expected compensation from the defendant. See TBI Unlimited, 2013 WL 12236, at \*4-5 (dismissing equitable claims where plaintiff "fail[ed] to make a showing of an expectation of compensation" from defendant); see also MK Strategies, 2007 WL 4322796, at \*3 (dismissing equitable claims where plaintiff failed to allege expectation of payment from defendant). Atlas does not allege it expected payment from Citibank. Rather, Atlas

only alleges it requested payment for work performed on the Citibank project solely from DXC. (ECF No. 16 ¶¶ 20, 22-23.) Nevertheless, Atlas contends they are not required to allege they expected payment from Citibank and instead may maintain a claim by alleging Citibank "passively received a benefit that it would be unconscionable to retain." (ECF No. 24 at 20.) However, in so arguing, Atlas inappropriately relies on Pennsylvania law. (*Id.*) As stated above, equitable claims under New Jersey law require an allegation of expectation of compensation. Therefore, because Atlas fails to make this allegation, their equitable claims against Citibank must be dismissed. Accordingly, Citibank's Motion to Dismiss Counts Three and Five of the Amended Complaint is **GRANTED**.

#### **IV. Conclusion**

\*5 For the reasons set forth above, Citibank's Motion to Dismiss is **GRANTED**. An appropriate order will follow.

#### **All Citations**

Slip Copy, 2020 WL 5105197

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### Tab 4

KeyCite Yellow Flag - Negative Treatment
Distinguished by Bell v. 3M Company, D.Colo., September 25, 2018
1998 WL 910271

UNPUBLISHED OPINION. CHECK COURT RULES BEFORE CITING.

Superior Court of Connecticut.

Thomas BOWERMAN, et al.,
v.
UNITED ILLUMINATING, et al.

No. X04CV 940115436S. | Dec. 15, 1998.

Memorandum of Decision on Defendants' Motion for Summary Judgment

#### KOLETSKY.

\*1 In fifteen separate lawsuits, approximately one hundred and nine plaintiffs filed personal injury actions against the defendants, United Illuminating Company (UI), ABB C-E Services, Inc. (ABB), New England Abatement Resources, Inc. (NEAR) and Allwaste Asbestos Abatement, Inc. (Allwaste), for their alleged exposure to asbestos while working at the Harbor Station Power Plant located in Bridgeport, Connecticut. The five plaintiffs in the case of Bowerman, et al v. United Illuminating, et al., No. X04-CV-94-0115436-S, and the five plaintiffs in the case of Goodall, et al. v. United Illuminating, et al., No. X04-CV-95-0115437-S, are the "test plaintiffs" for purposes of the defendants' motion for summary judgment.

The critical issue in this matter is whether the plaintiffs, who claim exposure to asbestos, can maintain an action in negligence absent the manifestation of symptoms of any asbestos-related disease.

In 1993, the plaintiffs worked at the Bridgeport Harbor Station as boilermakers, steamfitters, welders, plumbers or pipefitters. During the same period of time, an asbestos abatement project was undertaken at this UI facility. UI contracted with ABB, NEAR and Allwaste for repairs and asbestos removal. The plaintiffs claim that, because of the

actions of these defendants, they were exposed to asbestos and suffered injuries as a result thereof.

The amended complaint states three causes of action against each defendant: negligence; reckless and wanton misconduct; and intentional misconduct. The plaintiffs allege that, as a result of the defendants' conduct, they incurred the following injuries:

- 1. scarring of their lung tissue caused by inhalation of asbestos dust and fibers;
- 2. permanent implantation of [carcinogenic] asbestos fibers in plaintiffs' lungs;
- 3. an increased risk of developing lung cancer, mesothelioma, and other asbestos-related diseases; and
- 4. a present fear, apprehension and anxiety about developing asbestos-related diseases including cancer.

It is also claimed that they will incur future medical expenses relating to continuing medical surveillance to monitor whether plaintiffs' exposure causes health problems.

For the purposes of this summary judgment motion only, the plaintiffs and the defendant submitted a Joint Statement of Undisputed Facts dated April 17, 1998. In that document, the parties agreed to a number of facts, including the following: Asbestos abatement at the Harbor Station project was conducted from October 2, 1993 until November 25, 1993. The ten plaintiffs have not manifested physical symptoms of an injury, illness or disease that could be asbestos-related. Six of the ten plaintiffs have not been diagnosed with an injury, illness or disease that could be asbestos-related.

One plaintiff was diagnosed with bibasiliar fibrosis in 1990. Plaintiffs' medical expert reported this plaintiff revealed no evidence of an asbestos-related disease.

\*2 One plaintiff was diagnosed with a restrictive ventilatory defect, with borderline diffusing capacity, in 1994. Plaintiffs medical expert reported this plaintiff revealed no evidence of an asbestos-related disease.

Two of the plaintiffs have been diagnosed with an injury, illness or disease that could be asbestos-related. One plaintiff was diagnosed with pleural thickening on the right and

obstructive pulmonary impairment. The other plaintiff was diagnosed with 0/1 ILO reading and bilateral circumscribed pleural thickening.

None of the four plaintiffs referenced in the previous three paragraphs have had a doctor causally connect their conditions to asbestos exposure at Harbor Station. No plaintiff has undergone a lung tissue biopsy, received a medical diagnosis of lung tissue scarring as a result of his presence at Harbor Station or has received any treatment for asbestos-related injury, illness or disease. With the exception of one plaintiff, plaintiffs' claims for emotional distress arise solely from the fear of a future asbestos-related illness or disease.

The defendants filed a motion for summary judgment, with separate appendix, affidavits and exhibits, on May 1, 1998, seeking judgment on all counts of the plaintiffs' amended complaint, on the following grounds: 1) plaintiffs do not allege an actionable harm; 2) plaintiffs cannot prove to a reasonable degree of medical certainty that the defendants proximately caused their alleged injuries; 3) plaintiffs cannot recover for an increased risk of a future injury because they did not suffer a present injury; and 4) plaintiffs' claims of emotional distress are objectively unreasonable. The plaintiffs filed a memorandum in opposition, with accompanying attachments, affidavits and exhibits, on July 20, 1998. Thereafter, the defendants filed a reply to the plaintiffs' objection to the defendants' motion for summary judgment on August 10, 1998, and the plaintiffs filed a response to the defendants' reply, with accompanying affidavits, on August 21, 1998.

"Summary judgment shall be rendered forthwith if the pleadings, affidavits and any other proof submitted show that there is no genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of law ... In deciding a motion for summary judgment, the trial court must view the evidence in the light most favorable to the nonmoving party ... Although the party seeking summary judgment has the burden of showing the nonexistence of any material fact ... a party opposing summary judgment must substantiate its adverse claim by showing that there is a genuine issue of material fact together with the evidence disclosing the existence of such an issue ... It is not enough, however, for the opposing party merely to assert the existence of such a disputed issue. Mere assertions of fact ... are insufficient to establish the existence of a material fact and, therefore, cannot refute evidence properly presented to the court [in support of a motion for summary judgment]." (Citations omitted; internal quotation marks omitted.) *Home Ins. Co. v. Aetna Life & Casualty Co.*, 235 Conn. 185, 202-03, 663 A.2d 1001 (1995). "A 'material' fact has been defined adequately and simply as a fact which will make a difference in the result of the case." *Catz v. Rubenstein*, 201 Conn. 39, 48, 513 A.2d 98 (1986).

\*3 To successfully maintain an action in negligence, a plaintiff must demonstrate: 1) that the defendant has acted in a tortious manner; 2) that the plaintiff has sustained actual injury as a result of the defendant's actions; and 3) that the plaintiff knows of the causal connection between the defendant's tortious conduct and the resulting injury to the plaintiff. BellSouth Telecommunications, Inc. v. W.R. Grace & Co., 77 F.3d 603 (2nd Cir.1996); Dennis v. ICL, Inc., 957 F.Supp. 376, 379 (D.Conn. 1997). Regardless of any breach of a standard of care by a defendant, a compensable injury must occur in order for an action in negligence to survive. Barrett v. Danbury Hospital, 232 Conn. 242, 252-53, 654 A.2d 748 (1995). The initial question, therefore, is whether the scarring of lung tissue and implantation of asbestos fibers in the lungs due to asbestos exposure, as alleged in the plaintiffs' amended complaint, are compensable injuries as a matter of law. The plaintiffs claim that, although there are currently no physical symptoms of an asbestos-related disease, the inhalation of asbestos fibers caused a biological-physical harm to the lung tissue which has not yet manifested itself. There are no Connecticut cases addressing this precise issue.

An injury occurs when a party suffers some form of actionable harm, although the harm need not have reached its fullest manifestation for a cause of action to accrue. *Burns v. Hartford Hospital*, 192 Conn. 451, 460, 472 A.2d 1257 (1984). "Actionable harm occurs when the plaintiff discovers or should discover, through the exercise of reasonable care, that he or she has been injured and that the defendant's conduct caused such injury." *Champagne v. Rabestos-Manhattan, Inc.*, 212 Conn. 509, 521, 562 A.2d 1100 (1989).

As to what constitutes an "injury" or "harm," section 7 of the Restatement of Torts, Second, provides the following definitions:

The word "injury" ... denote[s] the invasion of any legally protected interest of another.

The word "harm" ... denote[s] the existence of loss or detriment in fact of any kind to a person resulting from any cause.

The words "physical harm" ... denote the physical impairment of the human body ...

In the "Comment" section of the Restatement, it is noted that "harm" implies "a loss or detriment to a person, and not a mere change or alteration in some physical person, object or thing. Physical changes or alterations may be either beneficial, detrimental or of no consequence to a person. In so far as physical changes have a detrimental effect on a person, that person suffers harm."

Although no Connecticut courts have had the occasion to rule upon the issue of whether or not the scarring of lung tissue and the implantation of fibers in the lungs due to asbestos exposure constitute a detrimental physical harm, there are decisions in other jurisdictions concluding asymptomatic plaintiffs have no actionable claims under such circumstances.

\*4 In Eagle-Picher Industries, Inc., v. Liberty Mutual Insurance, 682 F.2d 12, 18, (1st Cir.1982), the court noted that even when asbestos fiber becomes embedded in the lungs and the scarring process has begun, disabling disease or death is by no means inevitable. For this reason, many courts fail to recognize a viable claim until after some physical manifestation of an asbestos-related disease. In Borel v. Fibreboard Paper Products Corp., 493 F.2d 1076, 1102 (5th Cir.1973), for example, after remarking that a worker's present condition is the biological product of many years of exposure to asbestos dust, the court noted that "courts have consistently held that the cause of action does not accrue until the effects of such exposures manifest themselves."

The District Court in Hawaii was even more specific when it concluded that "the mere presence of asbestos fibers, pleural thickening or pleural plaques in the lung unaccompanied by an objectively verifiable functional impairment" is not an injury sufficient to support a claim for damages. *In re Hawaii Federal Asbestos Cases*, 734 F.Supp. 1563, 1567 (D.Hawaii 1990). Similarly, in *Simmons v. Pacor, Inc.*, 543 Pa. 664, 674 A.2d 232, 239 (Pa.1996), the Pennsylvania Supreme Court held that asymptomatic pleural thickening is not a compensable injury which gives rise to a cause of action. The court went on to say that the plaintiffs are not precluded, however, from subsequently commencing an action for an asbestos-related injury when symptoms develop and physiological impairment begins.

Plaintiffs' argument in the present case that, although asymptomatic, the plaintiffs have suffered some type of "pathological harm" due to their inhalation of asbestos, is an argument which has failed in the following cases. In Schweitzer v. Consolidated Rail Corp., 758 F.2d 936, 942 (3rd Cir.1985), the court held that "subclinical injury resulting from exposure to asbestos is insufficient to constitute the actual loss or damage to a plaintiff's interest required to sustain a cause of action under generally applicable principles of tort law." (Emphasis added.) In Bernier v. Raymark Industries, Inc., 516 A.2d 534, 543 (Me.1986), the court concluded that subclinical injury is not an actionable injury under tort law "even assuming that any inhalation of asbestos dust immediately causes microscopic injury to lung tissues ..." See also Anchor Packing v. Grimshaw, 115 Md.App. 134, 692 A.2d 5, 17 (Md.App.1997), wherein the court held that "cellular changes resulting from asbestos exposure, such as pleural plaques and thickening, alone" does not constitute a legally compensable injury.

Another line of cases denying relief for exposure without the manifestation of physical injuries involves claims brought pursuant to the Federal Employers' Liability Act (FELA). Although not controlling precedent in this case, those cases hold that actional injury under FELA does not exist until the accumulated effect of the inhalation of or exposure to deleterious substances manifests itself as a physical injury. Metro-North Commuter Railroad Co. v. Buckley, 521 U.S. 424, 117 S.Ct. 2113, 138 L.Ed.2d 560 (1997); Urie v. Thompson, 337 U.S. 163, 69 S.Ct. 1018, 93 L.Ed. 1282 (1949); Amendola v. Kansas City Southern Railway Co., 699 F.Supp. 1401 (W.D.Mo.1988). "The words 'physical impact' do not encompass every form of 'physical contact.' And, in particular, they do not include a contact that amounts to no more than an exposure ..." Metro-North Commuter Railroad Co. v. Buckley, supra, 2118.

\*5 There are other cases, however, in which the courts have concluded that whether such injuries as those alleged by the plaintiffs in the present case are actionable injuries is a question of fact rather than a matter of law. In *Bryson v. Pillsbury Co.*, 573 N.W.2d 718 (Minn.App.1998), the court held that the trier of fact should determine whether asymptomatic chromosome damage constituted a legally compensable present injury. The New Jersey Supreme Court, in *Caterinicchio v. Pittsburgh Corning Corp*. 605 A.2d 1092 (N.J.1992), concluded that the question was factual and remained within the province of the trier of fact because the plaintiffs' medical experts and the defendants' medical experts

disagreed on the critical issue whether the plaintiffs' pleural thickening and pleural plaques constituted a physical injury.

In another case, claiming damages based upon exposure to contaminated air and drinking water, the District Court in Minnesota stated: "[T]his Court cannot rule as a matter of law that plaintiffs' alleged injuries are not 'real' simply because they are subcellular. The effect of volatile organic compounds on the human body is a subtle, complex matter. It is for the trier of fact, aided by expert testimony, to determine whether plaintiffs have sufficient present harm." Werlein v. United States, 746 F.Supp. 887, 901 (D.Minn.1990). A Third Circuit decision, decided under Pennsylvania law, similarly concluded that with respect to asbestos-related pleural thickening, substantial medical disagreement over the classification of such a "condition" prevented the court from declaring it to be an injury as a matter of law. "This question is factual and remains within the province of the trier of fact." Howell v. Celotex Corp., 904 F.2d 5 (3rd Cir.1990).

This court is persuaded that the better line of reasoning warrants the conclusion that whether or not the scarring of lung tissue and implantation of asbestos fibers in the lungs constitute a compensable legal harm is an issue of fact if there is evidence showing such conditions to be detrimental and if there is evidence showing the existence of such conditions in the plaintiffs. Although the plaintiffs contend that their expert, Dr. Cullen, opined that a biological-physical harm occurs to the lung tissue almost immediately after the inhalation of asbestos fibers, an examination of his affidavits does not reveal any such statement. The nearest approximation appears to be the statement in paragraph 6 of his letter to Attorney Shafner dated July 9, 1998, wherein he says:

There is ample evidence that asbestos is ingested by certain cells within the respiratory tract and other organs which, in turn, leads those cells to incite an inflammatory response in their vicinity. Within the lung tissue, it is most likely that the inflammatory response itself initiates and promotes carcinogenesis in the epithelial cells, eventually leading to ... lung cancer ... In any event, I think that the best evidence at the present time suggests that within the lung, the most important aspect of carcinogenesis relates to inflammation and in the pleura, probably direct interaction and tumor initiation via genetic change.

\*6 Dr. Cullen, at paragraph 12 of his letter, addresses pleural changes.

Individuals who have asbestos-related pleural changes have, as a group, clearly experienced substantial asbestos exposure which is the basis for such pleural changes. In general, as a group, they are also reasonably older since it takes approximately 20 years from first exposure for the appearance of asbestos-related pleural changes. Having said that, in most epidemiologic studies which have looked at the question, individuals with pleural changes compared to co-workers without such pleural changes, appear to have a higher risk of developing asbestos-related malignancy. The basis for this is uncertain and may relate to the fact that as a group they have had more exposure to asbestos or may relate to the fact that as a group they have more evident biological responsiveness to asbestos than that group which has been exposed but has shown no pleural response. In any event, it is not that the pleural plagues are, themselves, are [sic] pre-malignant or auger malignancy, but only that they serve as a good marker for previous exposure and/or biologic responsiveness and, therefore, help us select a group which probably has a somewhat higher risk of developing lung cancer and/or mesothelioma than others who appear comparable in other ways.

The Court holds that Dr. Cullen's statements, taken as a whole, do not characterize the conditions alleged in plaintiffs' amended complaint as detrimental physical harms or state that those conditions constitute "bodily changes" as commented upon in the Restatement of Torts, Second.

Even if the Court were to conclude that Dr. Cullen's remarks are sufficient to establish that such conditions are detrimental and constitute an actionable harm, nothing has been submitted to demonstrate that these particular plaintiffs suffer from either of the alleged conditions. Simply stated, the plaintiffs have failed to put this matter in issue.

At oral argument on this motion for summary judgment, plaintiffs' counsel contended that it is a reasonable inference that some of the plaintiffs have asbestos fibers in their lungs. In addition, it is claimed that the opinions of Dr. Cullen expressed in his letters dated July 9, 1998 and August 18, 1998, support the plaintiffs' claims that they are reasonably certain to have suffered a harm due to their inhalation of asbestos and that these opinions are based upon reasonable medical probability rather than mere speculation or conjecture. The court disagrees.

The letters of Dr. Cullen speak generally to risks of exposure to asbestos. Nowhere can the statement be found that these

plaintiffs suffered scarring of the lung tissue and permanent implantation of asbestos fibers in their lungs as a result of their inhalation of asbestos at the Harbor Station. What he does say, at paragraph 11 of his letter dated July 9, 1998, is that he believes "it would be fair to say that even at the low levels postulated under the limited exposure assumption, there could be some biologic response to asbestos exposure in the men at the harbor station. I do not believe that his [sic] could be ascertained by any known clinical testing, including lung biopsy, in view of the fact that the changes are likely to be relatively slight compared to the normal variation seen in industrial workers who have been exposed to a wide variety of air pollutants and toxins over a working career."

\*7 Not only does this statement fail to rise above the level of "speculation and conjecture," but the plaintiffs' medical expert has even concluded that there is no way to demonstrate that these plaintiffs suffer from the conditions alleged in the amended complaint. His letter dated August 18, 1998, does nothing to further the plaintiffs' claims. He does give an opinion with respect to medical monitoring for these plaintiffs: "I have recommended medical monitoring of asbestos-exposed individuals at intervals appropriate to their level of exposure as I have for all asbestos-exposed individuals." His recommendation, therefore, is that medical monitoring is needed for anyone exposed to asbestos. He does not say that these particular plaintiffs require monitoring because of the biologic harms already incurred as a result of their exposure at the UI facility.

In addition to Dr. Cullen's affidavits, the individual plaintiffs have submitted affidavits in support of their objection to the defendants' motion for summary judgment. One of the affidavits (Affidavit of Samuel Ray) contains the statement: "I have trouble breathing from time to time, and I believe it is related to the asbestos exposure I have had throughout my 29-year career as a boilermaker." This subjective statement, without any medical documentation to support it, is insufficient to demonstrate that this symptom actually resulted from this plaintiff's claimed exposure to asbestos at the Harbor Station. It does not rise to the level of establishing a genuine issue of material fact as to whether the plaintiff's alleged asbestos exposure is the cause of his current shortness of breath. "The medical effect upon the human system of the infliction of injuries, is generally not within the sphere of the common knowledge of a lay witness ..." Aspiazu v. Orgera, 205 Conn. 623, 631, 535 A.2d 338 (1987).

No causal connection has been shown between the inhalation of asbestos and the "harm" alleged to have been suffered by these plaintiffs. At the outset, one must show the fact of "damage." *Simon v. New Haven Board & Carton Co., Inc.,* 516 F.2d 303, 306 (2nd Cir.1975). Further, the plaintiffs must demonstrate that the defendants' actions were the proximate cause of the plaintiffs' injuries. *Fleming v. Garnett,* 231 Conn. 77, 85, 646 A.2d 1308 (1994). Proximate cause establishes a reasonable connection between the acts or omissions of the defendants and the harm suffered by the plaintiffs. *Stewart v. Federated Dept. Stores, Inc.* 234 Conn. 597, 662 A.2d 753 (1995).

"To be entitled to damages a plaintiff must establish a causal relation between the injury and the physical condition which he claims resulted from it ... This causal connection must rest upon more than surmise or conjecture ... A trier is not concerned with possibilities but with reasonable probabilities ... [The causal relationship between an injury and its later physical effects may be established] by the direct opinion of a physician, by his deduction by the process of eliminating causes other than the traumatic agency, or by his opinion based upon a hypothetical question." (Citations omitted.) Aspiazu v. Orgera, 205 Conn. 623, 630-31, 535 A.2d 338 (1987); Struckman v. Burns, 205 Conn. 542, 554, 534 A.2d 888 (1987); Budney v. Zalot, 168 Conn. 388, 388-89, 362 A.2d 861 (1975). "Any expert opinion that describes a 'condition' as possible or merely fifty-fifty is based on pure speculation." Aspiazu v. Orgera, supra, 632.

\*8 The plaintiffs have failed to meet the requisite standard of reasonable medical probability. Not only have they failed in demonstrating that these plaintiffs have lung scarring and implantation of asbestos fibers in their lungs, they have also failed to establish any connection between the defendants' alleged conduct and the harm they claim resulted from it. The plaintiffs "failed to prove the injur[ies], and therefore could not prove causation." *LaBieniec v. Baker*; 11 Conn.App. 199, 208, 526 A.2d 1341 (1987).

The plaintiffs' amended complaint also alleges that as a result of the defendants' conduct, the plaintiffs suffer an increased risk of developing lung cancer, mesothelioma, and other asbestos-related diseases.

"[I]n a tort action, a plaintiff who has established a breach of duty that was a substantial factor in causing a present injury which has resulted in an increased risk of future harm is entitled to compensation to the extent that the future harm is

likely to occur." *Petriello v. Kalman*, 215 Conn. 377, 397-98, 576 A.2d 474 (1990). A plaintiff is not burdened with proving the occurrence of the claimed future event is more likely than not, when it is a present risk rather than a future event for which damages are sought. *Id.*, 396, 576 A.2d 474. "[A] plaintiff may recover for the fear of future medical treatment and disability, as distinguished from a recovery for the future disability itself, even if there is only a possibility that such future treatment or disability will take place." *Goodmaster v. Houser*, 225 Conn. 637, 645, 625 A.2d 1366 (1993).

The plaintiffs fail in their claims for increased risk of future harm for the simple reason that they have failed to establish that they personally have suffered present injuries. Without a present injury, under the *Petriello* rationale, there can be no claim for an increased risk of future harm. Even if it is assumed that the scarring of lung tissue and implantation of asbestos fibers in the lungs are compensable present injuries, there is nothing to indicate these plaintiffs have suffered these injuries as a result of actions of the defendant.

The plaintiffs' cause is not furthered by the claim that many of the individual plaintiffs had previous exposure to asbestos and therefore face a higher risk for the development of asbestos-related diseases. Such an argument cannot prevail without the existence of a present injury. Furthermore, such a claim may actually preclude the establishment of proximate cause if a plaintiff's exposure in the present case was minimal in comparison to his total exposure to asbestos over his work life.

In the plaintiffs' amended complaint, it is alleged that their injuries include "a present fear, apprehension and anxiety about developing asbestos-related diseases including cancer" as a result of the negligent and intentional actions of the defendants. The parties' briefs make reference to the negligent and intentional infliction of emotional distress.

\*9 It is important to note at the outset that the claims of emotional distress have not been pleaded as separate causes of action. To support an action for negligent infliction of emotional distress, a plaintiff has "the burden of pleading and establishing that the defendant should have realized that its conduct involved an unreasonable risk of causing emotional distress and that that distress, if it were caused, might result in illness or bodily harm." *Morris v. Hartford Courant Co.*, 200 Conn. 676, 683, 513 A.2d 66 (1986). There are no such allegations made in the plaintiffs' amended complaint.

To sufficiently plead a cause of action for intentional infliction of emotional distress, it must be alleged: 1) that the defendant intended to inflict emotional distress, or that he knew or should have known that emotional distress was a likely result of the defendant's conduct; 2) that the conduct was extreme and outrageous; 3) that the defendant's conduct was the cause of the plaintiff's distress; and 4) that the emotional distress sustained by the plaintiff was severe. *DeLaurentis v. New Haven*, 220 Conn. 225, 266-67, 597 A.2d 807 (1991); *Petyan v. Ellis*, 200 Conn. 243, 253, 510 A.2d 1337 (1986). There are no such allegations in the plaintiffs' amended complaint.

For this reason, the emotional distress alleged to have been suffered by the plaintiffs must be treated as a claim for damages resulting from the alleged negligent and intentional conduct of the defendants. The emotional distress would be the fear of contracting an asbestos-related disease in the future as a result of past exposure to asbestos.

Because the plaintiffs failed to show that they have suffered any present injuries, a claim for emotional distress in this case could only survive if mere exposure to asbestos entitles a claimant to emotional distress damages. There are no Connecticut cases directly on point. The case of *Barrett v. Danbury Hospital*, 232 Conn. 242, 654 A.2d 748 (1995), however, does involve a claim for compensation based upon the plaintiff's fear of contracting a blood-borne disease as the result of the alleged negligent actions of the defendant. The plaintiff had been placed on a stretcher in the defendant's emergency room and came in contact with the blood from a prior patient because of a torn vinyl pad which covered the stretcher. The defendants moved for summary judgment and the court granted the motion.

Our Supreme Court affirmed the trial court's decision, noting that the "trial court did not grant the motion for summary judgment on the basis of a finding that there was no negligence on the part of the defendants. The trial court determined that, regardless of any breach of the standard of care by the defendants, a compensable injury did not result.... [E]ven if the applicable standard had been violated, the plaintiffs' alleged injuries were not compensable as a matter of law." *Id.*, 252-53, 654 A.2d 748.

\*10 The plaintiffs' claim that the fear arises from an increased risk of future asbestos-related diseases cannot succeed for the reasons previously discussed, i.e., the plaintiffs have made no showing of present injuries and therefore cannot prevail on a claim for an increased risk of

related injuries. *Goodmaster v. Houser*, 225 Conn. 637, 625 A.2d 1366 (1993); *Petriello v. Kalman*, 215 Conn. 377, 576 A.2d 474 (1990). For these reasons, the plaintiffs' claims of emotional distress are not viable.

With respect to the one plaintiff who actually has received treatment for emotional problems, there was no evidence submitted indicating an issue of fact as to a causal connection between the alleged actions of the defendants and the plaintiff's emotional distress.

Counsel for the plaintiffs conceded at oral argument that the claim for medical monitoring expenses does not stand alone. Recovery for such expenses would only be allowable if these plaintiffs have sustained actionable injuries. The court, having ruled that the plaintiffs have furnished no evidence showing the existence of such injuries, concludes that the claim for future medical expenses relating to continuing medical surveillance must fail.<sup>2</sup>

Although the plaintiffs' expert, Dr. Cullen, recommended medical monitoring for these plaintiffs in his letter dated August 18, 1998, he indicated he recommends such monitoring "for all asbestos-exposed individuals." He does not say these particular plaintiffs require monitoring because of the biologic harms already incurred as a result of exposure to asbestos.

The plaintiffs cite the case of *Doe v. Stamford*, 241 Conn. 692, 699 A.2d 52 (1997), in support of their claim for medical monitoring expenses. In *Doe v. Stamford*, the plaintiff police officer sought compensation for past and future unpaid medical testing and treatment under the Workers' Compensation Act (act) for injuries related to HIV exposure and tuberculosis. Our Supreme Court concluded that the plaintiff's exposure to an infectious disease constitutes a compensable "injury" under the act. The Court noted that the exposures were sustained in incidents that arose out of and occurred in the course of his employment. Further, the Court stressed the *humanitarian and remedial purposes of the Workers' Compensation Act*. For this reason, the court finds the *Doe v. Stamford* case inapposite to the case at bar.

These plaintiffs are not without a remedy. If and when symptoms of an asbestos-related disease manifest themselves, they can bring a cause of action for their injuries.

Prior to the enactment of General Statutes Sections 52-577a and 52-577c, the statute of limitations applicable to a cause of action based upon a claim of negligent exposure to

a substance such as asbestos was Section 52-584. That provision reads, in relevant part, as follows:

Limitation of action for injury to person or property

No action to recover damages for injury to the person ...
caused by negligence, or by reckless or wanton misconduct, ...
shall be brought but within two years from the date when the
injury is first sustained or discovered or in the exercise of
reasonable care should have been discovered, and except that
no such action may be brought more than three years from
the date of the act or omission complained of ... (Emphasis
added.)

A number of courts have construed the word "injury" in cases in which defendants have moved to dismiss plaintiffs' claims for failure to bring them within the time permitted by the statute. In those cases, the courts held that a cause of action does not accrue until the plaintiff suffers an "actionable harm." The "actionable harm" that would be the "injury" under Connecticut law occurs when the plaintiff discovers or should discover, in the exercise of reasonable care, that he or she has been injured and that the defendant's conduct caused that injury. Durrett v. Leading Edge Products, Inc., 965 F.Supp. 280 (D.Conn. 1997). A breach of duty by a defendant, and a causal connection between that defendant's breach of duty and the resulting harm to the plaintiff, are the essential elements of a negligence cause of action. They are, therefore, necessary ingredients for actionable harm which will result in the accrual of the action for limitation purposes. Catz v. Rubenstein, 201 Conn. 39, 513 A.2d 98 (1986).

\*11 Sections 52-577a and 52-577c were subsequently enacted by the legislature and are now the operative statutes for asbestos claims based upon product liability and personal injury caused by exposure. A plaintiff instituting a product liability claim against a product seller must bring suit within "three years from the date when the *injury*, death or property damage is first sustained or discovered or in the exercise of reasonable care should have been discovered ..." (Emphasis added.) Subsection (e) of Section 52-577a further provides, with respect to asbestos, that "no such action for personal injury ... may be brought by the claimant later than thirty years from the date of last contact with or exposure to asbestos." Again, "injury" has been construed to be first sustained, for purposes of Connecticut's statute of limitations, when the party suffers some form of actionable harm. Durrett, supra, 283. In Champagne v. Raybestos-Manhattan, Inc., 212 Conn. 509, 526-27, 562 A.2d 1100 (1989), the actionable

harm occurred when the asbestos-related disease became symptomatic.

In the present case, the applicable statute of limitations is section 52-577c. That provision reads, in relevant part, as follows:

Limitation of action for damages caused by exposure to a hazardous chemical substance or mixture or hazardous pollutant

(b) Notwithstanding the provisions of sections 52-577 and 52-577a, no action to recover damages for personal injury or property damage caused by exposure to a hazardous chemical substance or mixture or hazardous pollutant released into the environment shall be brought but within two years from the date when the *injury* or damage complained of is discovered or in the exercise of reasonable care should have been discovered. (Emphasis added.)

A cause of action accrues when the "injury" is discovered or should have been discovered, not from the date of the exposure. In construing the term "injury" in Section 52-577c, it is reasonable to conclude it would be given the same judicial interpretation applied to the term "injury" in General Statutes Sections 52-584 and 52-577a.<sup>3</sup>

A superior court decision, *Woodford v. Heritage Village*, 1994 WL 632464 (Conn.Super.), held that the two-year limitation period under this statute begins to run on the date the claimant discovered or should have discovered the injury, not the date the alleged negligent action of the defendant occurred. In *Woodford*, the plaintiff had been sprayed in the face with a pesticide, but nothing was submitted to show the injuries manifested immediately after her exposure to the pesticide.

Upon manifestation of symptoms causally related to exposure to asbestos, the two-year limitation period under Section 52-577c would begin to run, i.e., a cause of action for actionable injuries accrues at that point in time. If these plaintiffs do manifest symptoms of an asbestos-related disease, they are not without a remedy under the law.

As previously noted, plaintiffs' amended complaint alleges negligence; reckless and wanton misconduct; and intentional misconduct. The negligence claims against the defendants cannot survive this motion for summary judgment because the plaintiffs have failed to show that they have suffered actionable injuries or a causal connection between the alleged actions of the defendants and harm suffered by the plaintiffs. The causes of action based in reckless and wanton misconduct and intentional misconduct must fail for the same reasons. A legal or proximate causal connection between the conduct of a defendant and the resulting injury to the plaintiff is a necessary element of causes of action in recklessness. *Boehm v. Kish*, 201 Conn. 385, 390, 517 A.2d 624 (1986).

\*12 Because there has been no showing that these plaintiffs have suffered compensable harm, there can be no cause of action regardless of whether such conduct could be classified as negligent, reckless or intentional. A breach of a standard of care is immaterial if there are no compensable injuries. *Barrett v. Danbury Hospital*, 232 Conn. 242, 252-53, 654 A.2d 748 (1995). Additionally, "[n]o matter how negligent a party may be, if his act bears no causal relation to the injury, it is not actionable." *Esposito v. Schiff*, 38 Conn.App. 726, 730, 662 A.2d 1337 (1995); *LaBieniec v. Baker*, 11 Conn.App. 199, 206, 526 A.2d 1341 (1987).

"A plaintiff cannot transform a negligence count into a count for willful and wanton misconduct merely by appending a string of adjectives to allegations that clearly sound in negligence." Brown v. Branford, 12 Conn. App. 106, 110, 529 A.2d 743 (1987). "[Recklessness] is more than negligence, more than gross negligence. (Citation omitted.) ... Willful misconduct has been defined as intentional conduct designed to injure for which there is no just cause or excuse. (Citation omitted.) Its characteristic element is the design to injure either actually entertained or to be implied from the conduct and circumstances. (Citations omitted.) Not only the action producing the injury but the resulting injury also must be intentional." Dubay v. Irish, 207 Conn. 518, 532-33, 542 A.2d 711 (1988). Whether conduct amounts to willful, wanton and reckless misconduct becomes strictly a matter of law when the mind of a fair and reasonable man could reach but one conclusion. Id., footnote 10, 534, 542 A.2d 711.

A review of the plaintiffs' amended complaint reveals essentially the same allegations of misconduct for all three causes of action. The court finds that the conduct alleged does not rise to the level of reckless and wanton misconduct or intentional misconduct.

The court finds that the plaintiffs have failed to state a cause of action in negligence, reckless and wanton misconduct or intentional misconduct. The plaintiffs have not established the existence of a material fact that is in issue. Accordingly, the defendants' motion for summary judgment is granted.

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# Tab 5

2012 WL 1964452 Only the Westlaw citation is currently available. NOT FOR PUBLICATION United States District Court, D. New Jersey.

Edna Diane BOWMAN and Amy McHenry, Plaintiffs,

V.

RAM MEDICAL, INC., Amerimed Corp., Henry Schein, Inc., Marathon Medical Corp., Medline Industries, MMS-A Medical Supply Co., and Q-Med Corp., Defendants.

Civil Action No. 10-cv-4403 (DMC)(MF). | May 31, 2012.

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#### **OPINION**

#### DENNIS M. CAVANAUGH, District Judge.

\*1 This matter comes before the Court upon the motion by Defendants RAM Medical, Inc., Henry Schein, Inc., Marathon Medical Corp., Medline Indus., MMS–A Medical Supply Co. and Q–Med Corp. (collectively, "Defendants") (ECF No. 34) to dismiss Plaintiff's complaint (ECF No. 1), filed on January 31, 2011. An amended motion to dismiss was filed by Defendants on September 30, 2011 (ECF No. 51). Defendant C.R. Bard, Inc. filed a motion to dismiss on April 23, 2012 (ECF No. 55). Pursuant to Fed.R.Civ.P. 78, which

states that the court has the authority to provide for submitting and determining the motions on briefs without oral hearings, no oral argument was heard.

#### I. Background

#### A. Factual Background

Defendants are in the business of marketing, distributing, selling, manufacturing or causing to be manufactured the surgical mesh at issue in this litigation. (Pl.'s Compl. ¶ 35, Aug. 26, 2010, ECF No. 1). Defendants, at all relevant times, allegedly sold surgical mesh as sterile, Food and Drug Administration ("FDA") approved, indicated for surgical use and Bard-manufactured. Id. at ¶ 36. Plaintiffs bring this action on behalf of themselves and putatively on behalf all other similarly situated persons "in the United States who had Defendants' counterfeit surgical mesh surgically implanted from September 1, 2007 until the present." (Pl.'s Compl. ¶ 26). The Complaint includes specific information about two Plaintiffs, Edna Diane Bowman and Amy McHenry. On December 1, 2009, Plaintiff Edna Diane Bowman underwent a surgical procedure at Lexington Medical Center in West Columbia, South Carolina ("LMC"), during which Defendants' counterfeit mesh was implanted in her body. Id. at ¶ 40. On February 23, 2010, Plaintiff Amy McHenry underwent a laparoscopic hernia repair procedure at LMC, during which Defendants' counterfeit mesh was implanted in her abdomen. Id. at ¶ 37. On July 19, 2010, Plaintiff Bowman received a letter from LMC informing her that the surgical mesh implanted during her surgery was "counterfeit surgical mesh." Id. at ¶ 51. On July 15, 2010, Plaintiff McHenry received a letter from LMC informing her of the same. Id. at ¶ 49.

Essentially, Plaintiffs claim that a counterfeit product was used during surgery without their consent or knowledge. However, Plaintiffs cite no physical injury or harm resulting. Plaintiffs state their claims in five counts including: (1) violation of the New Jersey Consumer Fraud Act ("NJCFA"), (2) unjust enrichment and common law restitution, (3) breach of express warranty, (4) breach of implied warranty of merchantability and (5) breach of implied warranty of fitness for a particular purpose. Plaintiffs contend the nature of the action involves false, misleading, inaccurate, deceptive and unconscionable commercial practices. (Pl.'s Compl. ¶ 1).

Plaintiffs explain that their belief was that the surgical mesh implanted was: (1) Bard-manufactured, (2) sterile, (3) approved for use by the FDA, and (4) indicated for surgical

use. (Pl.'s Compl. ¶ 47). Plaintiffs claim that in the condition in which Defendants sold their counterfeit mesh, the mesh had zero value. *Id.* at ¶ 48. Further, Plaintiffs state that had they known that Defendants' surgical mesh was not as represented, they would not have purchased, or agreed to purchase of the surgical mesh for use during the surgical procedures. *Id.* at ¶ 54. The only ascertainable loss Plaintiffs allege is the purchase price of a product they believed to be something else. *Id.* at ¶ 55. Plaintiffs vaguely state they "will incur [future] costs to repair the damages caused by Defendants' unlawful activity," but omit to further explain such "repairs." *Id.* 

\*2 Plaintiffs seek relief that includes: class certification; declarations that Defendants' unlawful actions violate the NJCFA, breach express and implied warranties of merchantability and implied warranties of fitness, and unjustly enrich Defendants; orders directing disgorgement of profits derived from unlawful practices, compelling Defendants to reimburse Plaintiffs in an amount equal to their ascertainable loss, and treble damages pursuant to N.J.S.A. 56:8–1 et seq.; restitution; and, attorney's fees. (Pl.'s Compl. ¶ 93).

#### **B.** Procedural Background

This matter comes before the Court upon the motion by Defendants RAM Medical, Inc., Henry Schein, Inc., Marathon Medical Corp., Medline Indus., MMS–A Medical Supply Co. and Q–Med Corp. (collectively, "Defendants") (ECF No. 34) to dismiss Plaintiff's complaint (ECF No. 1), filed on January 31, 2011. An amended motion to dismiss was filed by Defendants on September 30, 2011 (ECF No. 51). This Court *sua sponte* consolidated the *Calo Action* (Docket No. 11–cv–7381) with this matter on April 17, 2012.

Defendant C.R. Bard, Inc. filed a motion to dismiss on April 23, 2012 (ECF No. 55). Plaintiff Irene Kirk Calo then filed a motion to voluntarily dismiss her action, without prejudice, on May 21, 2012 (ECF No. 58), which this Court **granted** (ECF No. 58) pursuant to Fed. R. Civ. P. 41(a)(2).

Thereafter, Plaintiff Calo and C.R. Bard, Inc. stipulated to dismissal of Plaintiff's claims against C.R.Bard, Inc. with prejudice on May 29, 2012. Since Calo's motion for voluntary dismissal was granted on this day, this point is moot.

#### II. Standard of Review

In deciding a motion to dismiss, the District Court is "required to accept as true all factual allegations in the complaint and draw all inferences in the facts alleged in the light most favorable to [the Plaintiff]." Phillips v. Cnty. of Allegheny, 515 F.3d 224. 228 (3d Cir.2008V The Plaintiff's "obligation to provide the 'grounds' of his 'entitle[ment] to relief requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do." Bell Atl. Corp. v. Twombly, 550 U.S. 544, 555, 127 S.Ct. 1955, 167 L.Ed.2d 929 (2007). "[A court is] not bound to accept as true a legal conclusion couched as a factual allegation." Papasan v. Allain, 478 U.S. 265, 286, 106 S.Ct. 2932, 92 L.Ed.2d 209 (1986). Instead, when their truth is assumed, those factual allegations "must be enough to raise a right to relief above a speculative level." Twombly, 550 U.S. at 555. Plaintiff's obligation "requires more than labels and conclusions." *Id.* at 545. To survive a motion to dismiss, the complaint must state a plausible claim, not merely conclusory statements deriving from assumptions or inferences. Ashcroft v. Iqbal, 556 U.S. 662, 129 S.Ct. 1937, 1950, 173 L.Ed.2d 868 (2009).

In reviewing a motion to dismiss, it is well-established that a court should "consider only the allegations in the complaint, exhibits attached to the complaint, matters of public record, and documents that form the basis of a claim." *M & M Stone Co. v. Pa.*, 388 Fed.Appx. 156, 162 (3d Cir.2010).

#### III. Discussion

#### A. Standing

As an initial matter, this Court must discuss whether jurisdiction is founded in this case, given the requirements of Article III. Defendants say Plaintiffs lack standing because they state no injury in fact. (Def.'s Am. Mot. Dismiss 1, Sept. 30, 2011, ECF No. 51). Under Article III, federal judicial power is restricted to cases and controversies. Sprint Commc'ns Co. v. APCC Servs., Inc., 554 U.S. 269, 273, 128 S.Ct. 2531, 171 L.Ed.2d 424 (2008). The case-or-controversy requirement means that Plaintiff must establish standing. Id. Without standing, the federal court lacks subject matter jurisdiction and must dismiss the action. Common Cause of Pa. v. Pa., 558 F.3d 249, 257 (3d Cir.2009). Article III standing requires adequate establishment of: 1) an injury in fact, 2) causation, and 3) redressability. Sprint Commc'ns, 554 U.S. at 273. An injury in fact involves a concrete and particularized and actual or imminent, as opposed to conjectural or hypothetical, invasion of a legally protected interest. Id. (citing Lujan v. Defenders of Wildlife, 504 U.S. 555, 560-1, 112 S.Ct. 2130, 119 L.Ed.2d 351 (1992). The

causation element of standing requires a connection between the alleged injury in fact and the alleged conduct of the Defendant. Id The redressable element means that it is likely, and not merely speculative, that the injury in fact would be remedied by the relief sought. *Id*.

\*3 Defendants, in their motion to dismiss, explain how Plaintiffs fail to adequately establish the injury in fact element of standing:

In the instant matter, [P]laintiffs summarily allege that they "will incur costs to repair the damages caused by [D]efendants' unlawful activity" [ (Pl.'s Compl. ¶¶ 55 and 64) (emphasis omitted) ] without any indication of when or why such costs might be incurred, and while explicitly excluding any allegations of personal injury, either present or future. [ (Pl.'s Compl. ¶ 10) ] ... Plaintiffs have not alleged present, manifest or even imminent damages, or any adverse consequences whatsoever. The allegations are purely subjective and hypothetical. (Def.'s Am. Mot. Dismiss 7).

Plaintiffs counter that the injury in fact is the cost of buying a product that they would not have bought, had facts that arose later been apparent at the time when they could have made a choice. (Pl.'s Opp'n 10, Mar. 28, 2011, ECF No. 37). In the same vein, Plaintiffs argue that they received something other than what was bargained for. *Id*.

Defendants supply strong argument showing that Plaintiffs fail to adequately establish that the instant scenario demonstrates injury in fact. On the spectrum of proof relevant to injury in fact, Plaintiffs' case presents more of an "abstract" notion of injury, rather than a harm that is "distinct and palpable." See Whitmore v. Arkansas, 495 U.S. 149, 155, 110 S.Ct. 1717, 109 L.Ed.2d 135 (1990) (citing Warth v. Seldin, 422 U.S. 490, 501, 95 S.Ct. 2197, 45 L.Ed.2d 343; and O'Shea v. Littleton, 414 U.S. 488, 494, 94 S.Ct. 669, 38 L.Ed.2d 674 (1974)). Indeed, it can be assumed from the complaint that Plaintiffs might not have even discovered that "counterfeit mesh" was implanted without the letter from LMC describing the situation as such. Though Plaintiffs cleverly oscillate between contract and tort theories in an attempt to show that a harm amounts to "injury in fact" as envisioned under the standards for Article III standing, their arguments fall short of concrete proof.

Thus, this Court lacks subject matter jurisdiction over Plaintiffs claim and must dismiss. Though no further analysis is required due to the lack of subject matter jurisdiction, this Court will engage in a brief analysis of each Count of the Complaint.

### B. Count I: Violation of the New Jersey Consumer Fraud Act ("NJCFA")

Plaintiffs argue that their NJCFA claims are distinct and sustainable based on an economic injury theory, given they paid a premium for a product based on Defendants' misrepresentations. *See Id.* at 9; *see also Medley v. Johnson & Johnson Consumer Cos., Inc.*, No. 10–cv–2291, 2011 WL 159674, at \*2 n. 2 (D.N.J. Jan.18, 2011) (DMC). Plaintiffs will not establish the elements required by the NJCFA based on the fact that their allegations are "founded in the principals of economic inequities, not tort ..." (Pl.'s Opp'n 5). A claim under the NJCFA requires proof of: 1) an unlawful practice as defined under the Act; 2) ascertainable loss of moneys or property; and 3) a causal relationship between Defendant's unlawful conduct and Plaintiff's ascertainable loss. N.J.S.A. 56:8–19 (1998).

\*4 Plaintiffs state that Defendants' business practice of marketing, advertising and promoting counterfeit surgical mesh is "false, misleading, inaccurate and deceptive." (Pl.'s Compl. ¶ 58). However, Plaintiffs oppose Defendants' motion to dismiss with argument that focuses almost exclusively upon the heightened pleading requirement Defendants' suggest, and not at all upon the supplemental evidence that would buttress Plaintiff's otherwise conclusory claims. The NJCFA requires an unlawful practice such as an affirmative act, a knowing omission or a regulatory violation. *Parker v. Howmedica Osteonics Corp.*, 2008 WL 141628, \*2 (D.N.J. Jan.14, 2008) (citation omitted). Plaintiffs did not specifically allege any conduct that tends to amount to an "unlawful practice" under the NJCFA.

Otherwise fatal to Plaintiffs' claim is the failure of proof problem with the contention that they never received the benefit of the bargain or "paid for a product that was of no value." (Pl.'s Compl. ¶ 63). Such allegations do not satisfy the NJCFA's "ascertainable loss" requirement, without more. Though the "counterfeit surgical mesh" has a price tag, the "no value" concept of it, considering Plaintiffs do not assert any physical injury or otherwise, is abstract. Plaintiffs do not provide specific proofs of harm to support, or upon which this Court could infer a quantifiable loss. *Thiedemann v. Mercedes–Benz USA, LLC,* 183 N.J. 234, 252, 872 A.2d 783 (2005); *see also, Parker v. Howmedica Osteonics Corp.,* 2008 WL 141628, at \*3 (D.N.J. Jan.14, 2008). Stating the expectation of a future loss, similarly fails to meet the

requirement of the CFA, because it is too speculative. *Id.* This insurmountable problem is the same as that which precluded Plaintiff from establishing injury in fact tor standing purposes. Plaintiffs fail to state a claim under the NJCFA.

### C. Count II: Unjust Enrichment and Common Law Restitution

Plaintiffs may not sidestep Article III standing requirements by basing their claim in contract theory. Plaintiffs allege that they would not have purchased the product if it was not sterile, Bard-manufactured, FDA approved or indicated for surgical use. As such, Plaintiffs contend Defendants were unjustly enriched by their purchase and that they are therefore entitled to restitution. The parties point to a matter previously before this Court, Koronthaly v. L'Oreal USA, Inc., No. 07cv-5588, 2008 WL 2938045 (D.N.J. July 29, 2008), aff'd, 374 Fed.Appx. 257 (3d Cir.2010) (Plaintiff asserted lipstick products contained lead in far greater amounts than permitted in candy by the FDA). The Third Circuit reviewed a similar issue of whether a consumer could recover on the basis that she did not know what she was getting or would not have purchased the product had she known certain details about it. Koronthaly, 374 Fed. Appx. at 258. In a short opinion, the Court held that the purchases were not made pursuant to a contract and therefore Plaintiff had failed to prove that that which would have precluded her from buying the product had formed part of the basis of any bargain. Id. at 259. Plaintiff's claim failed because she did not demonstrate a concrete injury in fact, and it could not otherwise be sustained by artful pleading dependent upon contract theory. Id. Despite Plaintiffs' contentions that this case is distinguishable from Koronthaly, the fact that Plaintiffs did not actually received the product they intended to purchase and paid for, does not affect Plaintiffs' failing contract claims. Rather, the Third Circuit guides that the focus is upon the harm, or in this case, the lack thereof, rather than the buyer's expectation.

#### D. Count III: Breach of Express Warranty

\*5 Plaintiffs fail to demonstrate specifically that they relied upon labeling or other expressions of promise that could have formed the "basis of the bargain." Plaintiffs frame their breach of express warranty claim almost identically to their breach of implied warranty claims. In other words, Plaintiffs submit no specific proof of promises that were expressed, whether they amounted to, as Plaintiffs suggest, assertions that the

product was (1) Bard-manufactured, (2) sterile, (3) FDA approved, (4) indicated for surgical use or otherwise. Rather, Plaintiffs frame their claims upon assumptions of promise and information that the surgical mesh used was counterfeit. Establishing an express warranty requires more substantial proof. Indeed, the Third Circuit held that breach of an express warranty sounds in breach of contract and, as such, Plaintiffs' claim foils for reasons similar to those described in the prior section. *Pritchard v. Liggett & Myers Tobacco Co.*, 350 F.2d 479, 484 (3d Cir.1965). This Court will not assume, even considering LMC's concession that the mesh was counterfeit, that these four expressions were specifically made and relied upon. Such a lack of specificity does not comport with the nature of the theories supporting consumer reliance upon an express warranty.

#### E. Counts IV and V: Breach of Implied Warranty of Merchantability and Fitness for a Particular Purpose

Defendants convince this Court that, standing alone, the counterfeit nature of the surgical mesh "does not demonstrate that [Plaintiffs] or others could not use the product safely." (Pl.'s Opp'n 27). Plaintiffs do not supply any supporting facts, other than the counterfeit designation of the mesh, rendering the product valueless or unfit. Finally, Plaintiffs fail to assert any injury, and in fact disclaim any physical harm, resulting from the product. Plaintiffs again rely on the abstract concept of the mesh's "zero value" without proving specifically how the product failed. Plaintiffs further tail to show that the product is generally or otherwise unfit for the ordinary purpose which it was used. Rather, Plaintiffs declare that the surgical mesh continues to work for the purpose for which it was designed, to this day, despite any misrepresentations or omissions regarding the brand or otherwise. Plaintiffs can sustain neither a claim of breach of implied warranty of merchantability nor fitness for a particular purpose.

#### IV. Conclusion

For the foregoing reasons, this Court hereby **grants** Defendants' motion to dismiss Plaintiff's complaint. An appropriate order, filed on this day, follows this opinion.

#### **All Citations**

Not Reported in F.Supp.2d, 2012 WL 1964452

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## Tab 6

KeyCite Yellow Flag - Negative Treatment
Distinguished by U.S. v. Marshall Medical Center, E.D.Cal., May 12, 2015
2015 WL 106255

Only the Westlaw citation is currently available. United States District Court, N.D. California.

UNITED STATES of America, EX. REL. CAMPIE et al., Plaintiffs,

v.
GILEAD SCIENCES,
INC., et al., Defendants.

No. C-11-0941 EMC | Signed 01/07/2015

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### ORDER GRANTING DEFENDANTS' MOTION TO DISMISS

(Docket No. 58)

EDWARD M. CHEN, United States District Judge

#### I. INTRODUCTION

\*1 Pending before the Court is Defendants Gilead Sciences, Inc. and Gilead Sciences ULC's (collectively "Gilead") motion to dismiss Relators Jeff Campie and Sherilyn Campie's ("Relators") first amended complaint ("FAC") for failure to state a claim. Docket No. 58. Relators are current and former employees of Gilead. Gilead is a pharmaceutical company who, inter alia, supplies federal and state sponsored Medicaid and Medicare programs with drugs for the treatment of HIV/AIDS, cystic fibrosis, and hepatitis, among other serious illnesses. The first amended complaint alleges that Relators discovered, and reported to Gilead officials, numerous serious violations of Federal Food and Drug Administration ("FDA") regulations. Relators allege that Gilead failed to correct these violations, but rather concealed them and that the resulting sale of misbranded, adulterated drugs render each sale of the affected drugs "false" for purposes of the federal False Claims Act and related state laws. Relators further allege that Gilead retaliated against Relator Jeff Campie for his reporting the various FDA violations. Gilead has moved to dismiss Relators' FAC in full. For the foregoing reasons, Gilead's motion will be **GRANTED**, but Relators will be afforded leave to amend.

#### II. FACTUAL & PROCEDURAL BACKGROUND

A. Parties

Plaintiff—Relator Jeff—Campie is a former Senior Director of Global Quality Assurance for Defendant Gilead Sciences, Inc. FAC ¶ 5. Mr. Campie was employed by Gilead between 2006 and mid–2009. *Id.* While employed with Gilead, Mr. Campie had quality control oversight of (1) all commercially released drug products released by Gilead; (2) Gilead's polices, practices and Good Manufacturing Practices ("GMP") compliance; and (3) the development of quality systems. *Id.* Plaintiff—Relator Sherilyn Campie began working for Gilead in March 2007 as a Senior Research Associate. *Id.* ¶ 6. She still works for Gilead and is Associate Manager, Quality Control where she oversees the stability program for drug products in development in clinical phase trials. *Id.* 

Defendant Gilead is a California corporation that develops, manufacturers, promotes, and sells prescription drugs, with a focus on drug products for patients with life threatening diseases, such as HIV/AIDS, Hepatitis, cystic fibrosis, and cardio-pulmonary conditions. *Id.* ¶ 12. Gilead contracts with numerous companies for the manufacture of "active pharmaceutical ingredients" ("APIs") and other products that

go into the pharmaceutical products Gilead manufactures and sells. *Id.* The majority of prescriptions for Gilead's drugs are paid for by the federal and state governments through the various health care programs. *Id.* 

B. Summary of Relators' Allegations Regarding Gilead's Alleged FDA Violations

Notwithstanding Federal Rule of Civil Procedure 8's command that a complaint contain only a "short and plain statement of the claim," Relators' FAC is a sprawling 191 page, 747 paragraph document that consists largely of a laundry list of alleged FDA violations in immense detail. See Fed.R.Civ.P. 8(a). Given the nature of Gilead's challenge to the FAC, the Court need not walk through all of the alleged FDA violations in detail. Rather, the Court provides the following examples of Relators' allegations.

- 1. Alleged Use of Unregistered Manufacturing Facilities
- \*2 Relators allege that in or around 2008, Gilead contracted with Synthetics China, LTD to manufacture the API "emtricitabine," (commonly known as "FTC"). *Id.* ¶ 51. FTC is the active ingredient in many of Gilead's HIV/AIDs drugs, such as Emtriva, Truvada, and Atripla as well as several clinical trial drugs. *Id.* Synthetics China produced FTC at roughly half the cost as Gilead's existing suppliers and Gilead allegedly began using Synthetics China to save money and to trigger price reduction clauses in contracts with other FTC suppliers. *Id.* Gilead ultimately received approval from the FDA to use Synthetics China as an API manufacturer, but according to Relators, Gilead had been including products from Synthetics China in its finished drug products for at least two years before this approval was obtained. *Id.* ¶ 53.

Relators also allege that Gilead falsified or concealed data in support of its application to use Synthetics China as an API manufacturer. For example, in this application, Gilead claimed that it had received three full-commercial-scale batches of FTC from Synthetics China that had passed testing and were consistent with/equivalent to FTC batches made from existing manufacturers. *Id.* Relators contend that this representation was false and that two of the three batches had failed internal testing. *Id.* ¶ 57. One of the batches purportedly contained "residual solvent levels in excess of established limits" and other impurities. *Id.* A second batch had "microbial contamination" and showed the presence of "arsenic, chromium and nickel contaminants." *Id.* Relators allege, nonetheless, that this batch was released for final drug processing and commercial sale. *Id.* Despite being

aware of manufacturing problems at Synthetics China, Gilead allegedly released 77 lots of FTC produced by Synthetics China to its contract manufacturers well before FDA approval of the Synthetics China facility. *Id.*  $\P$  62, 65.

Relators allege that Gilead actively concealed its use of FTC produced by Synthetics China in a number of ways. First, Gilead imported the FTC at issue through its Canadian facilities (Gilead Alberta) and represented through fraudulent labeling that it was "API supporting Investigational New Drug ... activities" rather than its true use—API for commercial sales. *Id.* ¶ 70. Second the labels and paperwork for the API was obscured/augmented by the Gilead Alberta shipping paperwork to conceal where the FTC was actually produced. *Id.* ¶ 71. Third, Gilead credited its approved FTC manufacturer Yuhan with the production of the FTC—rather than the true producer, Synthetics China. *Id.* ¶ 72. During this time, Yuhan actually produced no FTC. *Id.* 

Relators contend that Gilead's false and misleading statements made in connection with the application to use Synthetics China as an API manufacturer—specifically, failing to disclose its prior use of Synthetics China and its labeling fraud—"infects each and every batch of final drug product in which Synthetics China's API was included" and thus makes every sale of such final drug to federal or state governments a violation of the False Claims Act and related state laws. *Id.* ¶¶ 76, 77.

Similar to the allegations regarding Synthetics China, Relators allege that Gilead used its Gilead Alberta facilities to produce the API ambrisentan two years before the Gilead Alberta facilities were approved by the FDA. *Id.* ¶ 78. Gilead was aware of quality issues with the API produced in this facility—including through patients complaints—but "revised" purity values in the applicable Certificate of Analysis ("COA") to hide these issues. *Id.* ¶¶ 98, 99, 101. Relators contend that every sale by Gilead to a government that incorporated ambrisentan manufactured at Gilead Alberta prior to FDA approval violated the False Claims Act and related state law.

- 2. Adulteration or Contamination in Gilead's Commercial Drug Products
- \*3 Relators' FAC alleges numerous instances of Gilead API or final drug products used in commercial sales being adulterated or contaminated. The following are two examples emblematic of Gilead's conduct as alleged by Relators.

#### a. Allegations Regarding FTC Contamination

As mentioned above, FTC is the API used in Gilead's drugs branded as Emtriva, Truvada, and Atripla (as well as combination drugs based on these three products). *Id.* ¶ 105. Prior to these drugs being approved, Gilead submitted New Drug Applications ("NDA") which listed FTC as an active ingredient and also listed a number of inactive ingredients. *Id.* ¶ 107. The FDA requires that every batch of final drug product contain identical active and inactive ingredients as those listed in the NDA. *Id.* Were a subsequent batch to contain ingredients not listed in the NDA, that product would be "misbranded" in violation of federal law. *Id.* For this reason, Relators contend that the sale of contaminated or adulterated drugs violate federal law. The FAC contains allegations of a number of instances of Gilead's FTC being contaminated.

For instance, Relators contend that Gilead was aware of an impurity known as "cyclic-FTU" that manifested in FTC when FTC was exposed to elevated humidity or temperatures. Id. ¶ 109, 110. Starting in mid–2003, Gilead began to observe "black specks" (or "charred and degraded particles") in its FTC. Id. ¶ 110. Relators allege that Gilead failed to disclose the presence of cyclic-FTU—or the fact that its FTC were failing internal testing—to the FDA. Id. ¶¶ 113, 114. They further contend that Gilead failed to "assess the longterm health consequences of the contamination and failed to establish a testing method for measuring the level of cyclic-FTU impurities." Id. ¶ 118. Relators thus allege that by no later than 2003, most if not all of the FTC batches used to manufacturer Gilead's drug products were "adulterated" with a variety of unapproved contaminants, including cyclic FTU. Id. ¶ 112. Despite the fact that the affected FTC lots were adulterated and had failed potency and purity testing, Relators contend that Gilead approved them for use in manufacture without further investigation, considering the black specks to be no more than aesthetic defects. Id. ¶ 122-23, 26. While Gilead finally fully disclosed the cyclic-FTU contamination to the FDA in 2010,  $^{1}$  id. ¶ 128, Relators allege that Gilead assured the FDA, that "no field alert report or recall was warranted" despite the fact that the presence of cyclic-FTU altered the chemical composition of its products and no changes had been made to its manufacturing processes to fix the issue. *Id.* ¶ 129.

Relators appear to allege that Gilead at least partially disclosed the presence of "degradation product(s)" had been observed in one of its products in 2005. *Id.* ¶ 118.

However, they contend that Gilead falsely represented the impurity was only seen when the drugs were stored in elevated temperature conditions. *Id.* In fact, the impurity had been observed in drugs even stored in normal temperature conditions. *Id.* 

Similarly, in 2010, Relator Sherilyn Campie allegedly observed three "unknown impurities" in additional FTC lots, and yet Gilead instructed its technicians to ignore the impurities. Id. ¶ 132. As a result, they were never identified, quantified, or reported to the FDA. Id. ¶ 135. Further, Relators allege that in November 2011, Gilead became aware that FTC lots used to validate Synthetic China's new, larger facility (known as "Plant 203") were "grossly contaminated" with "pinkish-orange particles," brown paper strips, blue colored glass, cement and fibrous building materials, and metal shards. Id. ¶¶ 156, 160. Relators allege that at least two of the validation lots from Plant 203 had already been released in the United States for commercial sale. Id. ¶ 154. While Gilead allegedly issued an "FDA field alert" about these lots, they "did not make any effort to recall them." Id. ¶ 155. Gilead began sieving and reprocessing those lots of contaminated API which it still had from the Synthetics China plant in question, resulting in kilograms of material being filtered. Id. ¶ 161. The API was then utilized in commercial production -Relators allege that Gilead failed to destroy any of the API after sieving. Id. ¶ 162. Relators further allege that Gilead took steps to alter the affected API's identification numbers to "give the appearance that they originated at the Gilead Alberta facility rather than the Synthetics China location under scrutiny." Id. ¶ 163.

\*4 Relators assert in their FAC that all of the NDAs for drugs which incorporate FTC contained "false statements and material omissions, in that they listed ingredients" that did not include cyclic-FTU, methylene-bridged impurities, or the other impurities and contaminants as referenced throughout the complaint. *Id.* ¶ 138. They allege that had the FDA known of these false statements and material omissions (or had it been aware of the adulteration), the FDA would not have approved the drugs or would have withdrawn approval. *Id.* ¶ 140. Relators further assert that the sale of the drugs containing the contaminated FTC would have been illegal under federal law as the drugs were "misbranded." *Id.* ¶ 144. Accordingly, Relators assert that all claims presented to the federal or state governments are "false claims" in violation of the False Claims Act and related state law claims. *Id.* ¶ 142.

Similarly, the Relators contend that Gilead certified in its certificate of analysis ("COA")<sup>2</sup> for drugs which incorporated

the Plant 203–produced FTC that the API was "in compliance with cGMP [current good manufacturing practice] and manufactured according to specifications in the NDA." *Id.* ¶ 174. However, as discussed above, it is alleged that Gilead knew this FTC was, in fact, contaminated by 2011. *Id.* They allege that had the FDA been notified of these false and material statements in the COA, it would not have approved Plant 203, or would have withdrawn approval. *Id.* ¶ 175. Accordingly, relators contend that all sales of drugs containing FTC from Plant 203 were "false claims" within the meaning of the False Claims Act and related state law claims. *Id.* ¶ 176.

According to the complaint, "[f]or every released batch of API or finished drug product, manufacturers are required to create a Certificate of Analysis ("COA") certifying that the batch was manufactured according to the specifications contained either in an Investigational New Drug ("IND") application or in a New Drug Application ("NDA")." FAC ¶ 32.

#### b. Allegations Regarding TDF Contamination

In April 2001, Gilead submitted an NDA to the FDA for approval of its drug "Viread"—a drug used to treat HIV and Hepatitis B. *Id.* ¶ 179. The FDA approved Viread for commercial sale and clinical use in October 2011. *Id.* The active ingredient of Viread is tenofovir disoproxil fumarate ("TDF"). *Id.* ¶ 181.

While the NDA for Viread was pending, Gilead was aware that black particles had been discovered in numerous Viread tablets manufactured at by its contractor Patheon. Id. ¶ 180. These batches showed "clear adulteration and contamination" insofar as none of the active or inactive ingredients was black—TDF is a "white to off-white crystalline powder." *Id.* ¶ 181. Later testing eventually showed that the specks in question consisted of teflon, charred TDF, acetaminophen, metal shavings, and other materials. Id. ¶ 185. Gilead used the contaminated TDF lots to validate its NDA submission for Viread and eventually sold the affected Viread tablets into the commercial market without ever disclosing the existence of the black particles. Id. ¶ 180, 184. Affected lots of TDF were also incorporated into validation batches of Gilead's drug Truvada and Atripla that were produced in connection with the filing of the NDAs for those drugs. *Id.* ¶ 187.

Gilead allegedly justified internally its failure to disclose the black particles to the FDA (or to list them as additional ingredients) by referring to them as "aesthetic defects." *Id.* ¶ 188. In 2008, Relator Jeff Campie had an independent forensic lab analyze samples from 8 batches of commercially released Viread and Truvada tablets which showed black particles in the tablets. *Id.* ¶ 191. The results showed that one particle was steel swarf, another particle was identified as steel wire, and the remaining particles were "composed of chromium nickel, stainless steel, titanium, chromium, iron, and cobalt." *Id.* ¶ 192. Despite the result of this test, Gilead found that the black particles occurred at a sufficiently low frequency so as to constitute only an "aesthetic defect." *Id.* ¶ 193. Relators allege that in September 2010, the FDA issued a warning letter to Gilead regarding visible contaminants in the company's drugs manufactured in one of Gilead's facilities. *Id.* ¶ 194.

\*5 Relators contend that because Gilead's NDAs for drugs using TDF did not list the black specks as an "ingredient," (1) the NDAs were false and fraudulent; (2) the FDA would not have approved the drugs (or would have withdrawn its approval) had it known about them, and therefore all claims presented to federal and state government relating to these drugs constitute "false claims." *Id.* ¶ 199.

#### 3. Adulteration or Contamination in Gilead's Clinical Drug Products

In addition to the above contamination issues involving Gilead's commercially sold drugs, Relators allege a number of instances of contamination in Gilead's drug products used in clinical trials. The following are two examples.

### a. Contamination in Viread Used During Pediatric Clinical Trials

As part of its approval of Viread, the FDA required that Gilead conduct clinical trials regarding the efficacy of Viread and TDF on pediatric patients infected with HIV. *Id.* ¶ 248. Beginning in 2002, Gilead began conducting this clinical trial. *Id.* ¶ 250. During the clinical trial, Relators contend that the Viread was made with TDF that contained "black particles, foreign matter, gross contamination, and visible filth" from unknown origins. *Id.* Gilead never reported this to the FDA, and instead certified the results of multiple studies. *Id.* Relators contend that Gilead was motivated to ensure that it obtain an NDA for pediatric use of Viread as well as a 6 month extension of patent exclusivity on the TDF molecule

from the FDA (worth approximately \$3 billion in sales). *Id.*  $\P$  270.

The "black and brown specks" were first observed in several lots of TDF in November 2002. Id. ¶ 252. Even though Gilead was unable to locate the source of the particles or how it was introduced into the manufacturing process, it nevertheless decided to go forward with manufacturing and only instructed its contractor to continue "appearance inspections" and sampling. Id. Eventually, Gilead suspended even these superficial inspections and sampling. Id. ¶ 254. TDF lots containing these contaminants were used in a number of clinical trials, such as a Phase III trial entitled "Safety and Efficacy of Switching from Savudine or Zidovudine to Tenofovir DF in HIV-1 infected children." Id. ¶ 257. The TDF lots used in this study were, according to internal chemistry memos, contaminated with "small black and reddish-brown particles" that Gilead believed to probably (though not definitively) be Teflon. Id. ¶ 258. Gilead concluded the particles were "cosmetic defects" that had no impact on the efficacy of the drug. Id. ¶ 259. Later testing of TDF manufactured from a contractor showed that the TDF API in this lot was also contaminated with acetaminophen ("APAP")—a drug that Eurand manufacturers in the same facility. Id. ¶ 262, 263. This lot was released for clinical use in July 2008. Id. ¶ 269.

Relators allege that Gilead never notified the FDA of the contamination issues (either the black/brown specks, the presence of Teflon, or the presence of APAP) and in January 2012, the FDA approved the NDA for pediatric use of Viread. *Id.* ¶ 272. Relators contend that had the FDA known of these issues, it would not have approved the drug formulation. *Id.* ¶ 275. Because of this, and because the presence of the contaminants rendered the Viread misbranded, Relators contend that any claims made to the federal or state governments regarding this drug are "false claims." *Id.* ¶¶ 277, 279.

#### b. Contaminated Hepsera Used in Pediatric Clinical Trial

\*6 As part of its approval of Hepsera, the FDA required Gilead to develop and conduct clinical trials for a pediatric formulation of its drug Hepsera for pediatric patients infected with Hepatitis B. *Id.* ¶ 281. During the clinical trial, Relators allege that Gilead utilized Hepsera containing the API adefovir dipivoxil ("adefovir DP") that failed stability testing regarding potency and purity. They also allege that the

placebos employed during the test had gross contamination, visible filth, and cadmium from unknown origins. *Id.* ¶¶ 282, 283. In addition, samples of adefovir DP from a lot produced in September 2002 began to fail internal testing for potency (76 %) and the presence of impurities (20%). *Id.* ¶ 288. Nonetheless, Gilead concluded the failed tests did not reflect on the suitability of the adefovir DP lot, simply terminated the internal testing condition, never reported the failed test results, and continued to use the adulterated lot in the clinical study. *Id.* ¶ 289.

At the same time as the above, Relators allege that foreign matter was also observed in a placebo batch used during the clinical study. *Id.* ¶ 290. Forensic testing of the affected batch revealed that the sample contained cadmium—a "critical" defect based on Gilead's internal classification. *Id.* ¶ 292. Nonetheless, Gilead did not reject and dispose of the batch, but rather released the placebo to the clinical study, labeling the contamination as "isolated" with "no conclusive evidence to pinpoint the source of the particle." *Id.* ¶ 295. Gilead never notified the FDA of the contaminated placebo used in the pediatric clinical trial. *Id.* ¶ 296.

Relators contend that had the FDA known about the impurities and contaminations in the Hepsera and placebo, it would not have approved the pediatric formulation of Hepsera. *Id.* ¶ 299. This, plus the fact the Hepsera was allegedly misbranded render any claims filed with the federal and state government for this drug to be "false claims.' *Id.* ¶¶ 301, 303.

#### III. DISCUSSION

#### A. Legal Standard

Under Rule 12(b)(6), a party may move to dismiss based on the failure to state a claim upon which relief may be granted. Fed.R.Civ.P. 12(b)(6). A motion to dismiss based on Rule 12(b)(6) challenges the legal sufficiency of the claims alleged. See Parks Sch. Of Bus. Symington, 51 F.3d 1480, 1484 (9th Cir. 1995). In considering such a motion, a court must take all allegations of material fact as true and construe them in the light most favorable to the nonmoving party, although "conclusory allegations of law and unwarranted inferences are insufficient to avoid a Rule 12(b)(6) dismissal." Cousins v. Lockyer, 568 F.3d 1063, 1067 (9th Cir. 2009). A claim must meet the standard addressed in Rule 8, and include "a short and plain statement of the claim showing that the pleader is entitled to relief." Fed.R.Civ.P. 8(a)(2). "Under the pleading

requirements of Federal Rule of Civil Procedure 8, [a court] must determine whether the complaint contains 'sufficient factual matter' that, taken as true, 'state a claim for relief [that] is plausible on its face.' " *United States ex rel. Lee v. Corinthian Colleges*, 655 F.3d 984, 991 (9th Cir. 2011) (citing *Ashcroft v. Iqbal*, 556 U.S. 662, 677 (2009)).

Additionally, when alleging fraud or mistake, a relator is held to a heightened pleading standard, and is required to "state with particularity the circumstances constituting fraud or mistake." Fed.R.Civ.P. 9(b). Because they involve allegations of fraud, qui tam actions under the FCA must meet not only the requirements of Rule 8, but also the particularity requirements of Rule 9. Corinthian Colleges, 655 F.3d at 992. Notably, Rule 9(b) requires only that the circumstances of fraud be stated with particularity; other facts may be pled generally, or in accordance with Rule 8. Id. The Ninth Circuit has joined the Fifth Circuit in concluding, in accord with the general pleading requirements under Rule 9(b), that it is sufficient to allege, "particular details of a scheme to submit false claims paired with reliable indicia that lead to a strong inference that claims were actually submitted." Ebeid ex rel. U.S. v. Lungwitz, 161 F.3d 993, 998–999 (9th Cir. 2010).

\*7 A relator must provide enough detail to give the defendant notice of the particular misconduct which is alleged to constitute the fraud charged so that they can defend against the charge and not just deny that they have done anything wrong. *Id.* The relator must also supply reasonable indicia that false claims were actually submitted. *Id.* The complaint must refer to the statute, rule, regulation, or contract that conditions payment on compliance with FDA regulations of drug production. *Id.* at 1000. Under Rule 9(b), allegations must include details and facts setting out the who, what, when, where, and how. *Id.* 

B. Gilead's Motion to Dismiss Relators' Federal False Claims Act Will Be Granted

As relevant to this action, the False Claims Act ("FCA") provides:

- (a) Liability for certain acts.—
  - (1) In general. —Subject to paragraph (2), any person who—
  - (A) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval;

is liable to the United States Government for a civil penalty of not less than \$5,000 and not more than \$10,000 ... plus 3 times the amount of damages which the Government sustains because of the act of that person.

31 U.S.C. § 3729(a). An FCA claim requires a showing of a(1) false statement or fraudulent course of conduct, (2) made with requisite scienter, (3) that was material, and (4) caused the government to pay out money or forfeit moneys due. *See U.S. ex rel. Hendow v. Univ. of Phoenix*, 461 F.3d 1166, 1174 (9th Cir. 2006).

Congress designed the FCA to "broadly ... protect the funds and property of the government" by preventing and punishing false or fraudulent conduct. Rainwater v. United States, 356 U.S. 590, 582 (1958); see also United States v. Bornstein, 423 U.S. 303, 309 n.5 (1976) ("According to its sponsor, the False Claims Act was adopted 'for the purpose of punishing and preventing ... frauds."). The FCA is "intended to reach all types of fraud, without qualification, that might result in financial loss to the Government." United States v. Neifert-White Co., 390 U.S. 228, 232 (1968). At the same time, however, the FCA is not a catchall anti-fraud provision—it " 'attaches liability, not to the underlying fraudulent activity or to the government's wrongful payment, but to the claim for payment.' " Cafasso, U.S. ex. rel. v. General Dynamics C4 Sys., Inc., 637 F.3d 1047, 1055 (9th Cir. 2011) (quoting United States v. Rivera, 55 F.3d 703, 709 (1st Cir. 1995)).

Gilead has moved to dismiss Relators' FCA claim, contending that Relators' allegations that Gilead committed various FDA regulatory violations fail, as a matter of law, to state a viable FCA action. Docket No. 58, at 7. They argue that at no point during the Medicare or Medicaid reimbursement process did Gilead certify (expressly or impliedly) that it had complied with FDA safety or GMP regulations. Accordingly, it contends there was no false or fraudulent statement made in connection with the request for reimbursement.

Relators respond that Gilead's alleged misconduct gives rise to an actionable FCA claim under three separate theories. Relators' first two theories assert that the reimbursement claims at issue in this case were "legally false" in that they were "tainted by some *underlying* statutory, regulatory, or contractual violation made in connection with [those] claim[s], which renders the claim[s] ineligible for reimbursement." *U.S. ex. rel. Kester v. Novartis Pharms. Corp.*, — F.Supp.2d —, 2014 WL 4230386, at \*4 (S.D.N.Y. Aug. 7, 2014) (emphasis added). First, Relators assert that the claims at issue are false insofar as Gilead

...

falsified information to the FDA, misrepresenting to the FDA compliance with FDA regulations at "virtually every stage of the supply-chain process." Docket No. 84, at 15. Second, Relators contend that they have stated a claim under a promissory fraud or "fraud-in-the-inducement" theory insofar as Gilead's fraudulent activity was used to obtain a federal benefit—namely, FDA approval of their drugs which was, in turn, used to get their drugs covered under Medicare and Medicaid (a prerequisite to payment). *Id.* Relators' final theory is one of factual falsity—asserting that Gilead knowingly supplied nonconforming drugs and misrepresented their quality to purchasers (who ultimately sought reimbursement from the government under Medicare and Medicaid). Docket No. 84, at 14–15.

1. Relators' False Certification and Promissory Fraud Theories Fail Because the Alleged Fraud Was Directed at the FDA, not the Centers for Medicare and Medicaid, the Payor Agency, Distinct from the Reimbursement Process

\*8 As detailed above, the FAC in this action contains sprawling allegations contending that Gilead has engaged in a widespread pattern of violating safety and GMP statutes and regulations promulgated (and enforced) by the FDA. However, the fact that Gilead may have knowingly violated these statutes and regulations, without more, does not suffice to state a FCA claim. "Violations of laws, rules, or regulations alone do not create a cause of action under the FCA." U.S. ex rel. Hopper v. Anton, 91 F.3d 1261, 1266 (9th Cir. 1996). Rather, it is the "false certification of compliance which creates liability when certification is a prerequisite to obtaining a government benefit." Id. And, as discussed below, the FCA requires that false certification (i.e., the false statement within the meaning of the FCA) be directed to the government as part of the reimbursement process. In the case at bar, the FDA was not the payor agency and was not directly involved in the reimbursement process.

False certifications<sup>3</sup> come in two varieties—express and implied—and either may form the basis of FCA liability. "Express certification" occurs when an "entity seeking payment certifies compliance with a law, rule or regulation as part of the process through which the claim for payment is submitted." *Ebeid*, 616 F.3d at 998. By comparison, "[i]mplied false certification occurs when an entity has previously undertaken to expressly comply with a law, rule, or regulation, and that obligation is implicated by submitting a claim for payment even though a certification of compliance is not required in the process of submitting the claim."

Id.; see also United States v. Empire Educ. Corp., 956 F.Supp.2d 248, 255 (N.D.N.Y. 2013) ("[A]lthough the claim for payment does not certify compliance with a statute or regulation on its face, compliance is a prerequisite to payment under the express statutory or regulatory terms."). To prove materiality under either theory Relators must demonstrate that the certification and compliance with the statutory, regulatory, or contractual provision was a "prerequisite to obtaining a government benefit" or the "sine qua non of receipt of state funding." Ebeid, 616 F.3d at 998 (quoting Hopper, 91 F.3d at 1266).

The term "certification" in this context does not carry with it any talismanic significance, but is "simply another way of describing a false statement made to the government." *Gonzalez v. Planned Parenthood of L.A.*, No. CV 05–8818 AHM (FMOx), 2012 WL 2412080, at \*4 (C.D. Cal. June 26, 2012); *see also U.S. ex rel. Hendow v. Univ. of Phoenix*, 461 F.3d 1166, 1172 (9th Cir. 2006) (rejecting view that the "word 'certification' has some paramount and talismanic significance").

In addition to the false certification theory of liability, the Ninth Circuit has recognized FCA liability based on promissory fraud or "fraud-in-the-inducement." Under this theory, no false statement regarding compliance with government regulations is needed, but rather, "liability will attach to each claim submitted to the government under a contract, when the contract or extension of government benefit was originally obtained through false statements or fraudulent conduct." U.S. ex rel. Hendow v. University of Phoenix, 461 F.3d 1166, 1173 (9th Cir. 2006). The Ninth Circuit has noted that this theory is "not so different from the false certification theory, and even requires the same elements." Id. at 1174.

Relators have failed to state a claim under the FCA under either a false certification or promissory fraud theory. Fundamentally, they have failed to allege that Gilead engaged in any fraudulent conduct or made any false statement to the Centers for Medicare and Medicaid Services ("CMS")—the governmental agency that administers reimbursement under the Medicare and Medicaid regimes— as part of a request for payment. *See Gundersen Luterhan Med. Ctr., Inc. v. Johnson,* No. 06–2195 TFH/DAR, 2009 WL 596974, at \*1 (D.D.C. 2009). In fact, at the hearing, Relators conceded that Gilead had not made any "direct misrepresentation to the payor." Transcript of October 21, 2014 Hearing at 44:1–3 (Docket No. 111). What Relators have alleged, instead, is that Gilead (1) falsely certified to the FDA during the drug

approval process that it would comply with GMP regulations while, at the same time, knowingly flouting those regulations and (2) withheld or falsified information and test results in various submissions to the FDA. The Court finds that false certifications, statements, or other fraudulent conduct directed at the FDA during the approval process do not render subsequent Medicare or Medicaid reimbursement requests made to CMS "false" under the FCA. Based on the plain text of the FCA and Ninth Circuit authority interpreting that language, the Court concludes that Relators have failed to state an FCA claim by failing to allege a false claim was made to CMS "for payment."

\*9 The FCA imposes liability on an individual who "knowingly presents, or causes to be presented, a false or fraudulent claim *for payment or approval.*" 31 U.S.C. § 3729(a)(1) (emphasis added). No circuit court, including the Ninth Circuit, has ever interpreted this statutory language as encompassing a false or fraudulent statement to a licensing or regulatory agency—disconnected from the request for payment—simply because that false or fraudulent statement to that licensing agency ultimately enabled the defendant to achieve eligibility for funding from the payor agency.

"Not every instance in which a false representation of compliance with a regulatory regime is made will lead to liability." U.S. ex rel. Kirk v. Schindler Elevator Corp., 601 F.3d 94, 114 (2d Cir. 2010), rev'd on other grounds 131 S.Ct. 1885 (2011). "The language of [the FCA] plainly links [a defendant's] wrongful activity to the government's decision to pay." Mikes v. Straus, 274 F.3d 687, 696 (2d Cir. 2001) (emphasis added); see also 31 U.S.C. § 3729(a) (1) (covering any person who "knowingly presents, or causes to be represented, a false or fraudulent claim for payment " (emphasis added)). Accordingly, a "false certification of compliance with a statute or regulation cannot serve as the basis for a qui tam action under the FCA unless payment is conditioned on that certification." U.S. ex rel. Siewick v. Jamieson Science & Engineering, Inc., 214 F.3d 1372, 1376 (D.C.Cir. 2000). Stated another way, "[t]here is no liability under [the FCA] for a false statement unless it is used to get [a] false claim paid." United States v. Southland Mgmt. Corp., 326 F.3d 669, 675 (5th Cir. 2003) (en banc).

The Ninth Circuit has recognized this principle by holding that FCA liability "cannot attach 'where regulatory compliance was not a *sine qua non* of receipt of state funding" and the statute at issue did " 'not require funding recipients to certify their compliance with federal law and regulations.'

"Ebeid, 616 F.3d at 997 (quoting Hopper, 91 F.3d at 1266). There must be a direct and immediate link between a false statement or fraudulent conduct and the resulting request for payment; payment must be conditioned on the falsity. Cf. Allison Engine Co. Inc. v. U.S. ex rel. Sanders, 553 U.S. 662, 672 (2008) (noting that the "direct link between the false statement and the Government's decision to pay or approve a false claim is too attenuated to establish liability" where a defendant makes a false statement without "intend[ing] the Government to rely on that false statement as a condition of payment" (emphasis added)).

The Ninth Circuit's decisions in Hendow and Ebeid provide useful examples of the type of direct link required between the alleged fraudulent conduct or statement and the request for payment. Hendow (an express certification case) involved federal subsidies under Title IV and the Higher Education Act. Hendow, 461 F.3d at 1168. The applicable statute and regulation at issue in conditioned a school's participation in the subsidy program on having the school enter into an agreement with the Department of Education in which the school agreed to "abide by a panoply of statutory, regulatory, and contractual requirements"—including a ban on the school paying recruiters incentive payments on a perstudent basis. Id. The defendant—the University of Phoenix —was alleged to have repeatedly certified to the Department of Education that it was in compliance with this incentive ban while intentionally and knowingly violating the ban. Id. The Court found these false certifications-made to the payor agency and entered into for the sole purpose of participating in a federal subsidy program—were sufficient to establish FCA liability because the "statute, regulation and agreement [there] all explicitly condition[ed] participation and payment on compliance with, among other things, the precise requirement that relators alleged that the University knowingly disregarded." *Id.* at 1167.

\*10 Similarly, in *Ebeid* (an implied certification case), the Ninth Circuit distinguished between statutes and regulations which could form the basis of an implied certification theory and those which could not. *Ebeid* involved a defendant health care provider who allegedly engaged in the unlawful corporate practice of medicine and made unlawful referrals to businesses in which the defendant had a "financial interest" in violation of the Stark Act, 42 U.S.C. § 1395nn(a)(1). *Ebeid*, 616 F.3d at 995. The Ninth Circuit concluded that the defendant's alleged "unlawful corporate practice of medicine" could not form the basis of FCA liability because the relator had failed to "refer to any statute, rule, regulation, or

contract that conditions payment on compliance with state law governing the corporate practice of medicine." Id. at 1000. As to the alleged violations of the Stark Act, however, the court found that the violations could "provide a valid basis from which to imply certification, because [the Act] expressly conditions payment on compliance." Id.; see also 42 U.S.C. § 1395nn(g)(1) ("No payment may be made under this subchapter for a designated health service which is provided in violation of subsection (a)(1) of this section."). Ebeid, therefore, involved allegations of an implicit certification that was directly tied by the applicable statutory language to the participation in a federal funding program and requests for payment. Because the Stark Act conditioned payment on compliance with the "financial interest" referral bar, every payment submitted to the paying agency by the defendant falsely implied certification of compliance with that bar.

In both Hendow and Ebeid the false statement or fraudulent conduct was made to an entity administering a federal funding program and as part of the process of obtaining payment from the government. In short, false claims were made "for payment." In contrast, Gilead's non-disclosures and misrepresentations were made to the FDA during the FDA approval process; this process preceded and was distinct to the subsequent reimbursement requests to CMS under Medicare or Medicaid. In short, the misrepresentations at issue were to the FDA, not the payor agency (CMS) and were not made as a condition of reimbursement by CMS. Unlike *Ebeid*, Relators here have not pointed to any law, regulation, or contract provision that conditions CMS's payment on Gilead's compliance with FDA quality assurance rules. Rather, payment is conditioned only on FDA approval of the drugs sold. Here, Gilead had obtained FDA approval of all the drugs in question.

Relators rely heavily on the *Hendow* court's statement that "'[i]f a false statement is integral to a causal chain leading to payment, it is irrelevant how the federal bureaucracy has apportioned the statements among layers of paperwork.' " *Hendow*, 461 F.3d at 1168 (quoting *U.S. ex rel. Main v. Oakland City University*, 426 F.3d 914, 916 (7th Cir. 2005)). Relators argue that approval of the drugs by the FDA was part of the causal chain which enabled Gilead ultimately to obtain reimbursement from CMS. However, *Hendow* (and the Seventh Circuit case it quoted) were dealing with a payment process that was separated into discrete steps requiring the submission of different applications. In context, the quote on which Relators rely stands for the proposition that a defendant cannot escape FCA liability for false statements

made to the payor agency simply because that agency divided the process into multiple stages. It does not stand for the proposition that a falsehood told to a governmental regulatory agency can form the basis of FCA liability simply because the fraudulently induced action of that agency was part of a causal chain that ultimately led to eligibility for payment from the payor agency. Such causation is insufficient to state a claim under the FCA. Cf. U.S. ex rel. Sikkenga v. Regence Bluecross Blueshield of Utah, 472 F.3d 702, 714 (10th Cir. 2006) (adopting a proximate causation standard "to determine whether there is a sufficient nexus between the conduct of the party and the ultimate presentation of the false claim to support liability under the FCA"). Nothing in Hendow eliminates the requirement under the FCA that the alleged fraud be made as part of a claim for payment to the payor agency.4

Liability based solely on cause-in-fact is not typical. Courts have implied limitations, such as requiring proximate cause, even where not expressly imposed by statute. *See Paroline v. United States*, 134 S.Ct. 1710, 1720 (2014). Here, the FCA requires the fraudulent claim be presented "for payment." 31 U.S.C. § 3729(a)(1).

Relators cite two district court cases where a misrepresentation to a third party in a "licensing role" was held to state a viable theory for FCA liability because of a subsequent request for payment made to a separate, payor agency. See, e.g., Amphastar Pharms. Inc. v. Aventis Pharma SA, No. EDCV-09-0023 MJG, 2012 WL 5512466 (C.D.Cal. Nov. 14, 2012) (finding allegations that an entity, inter alia, made false representations to the PTO and FDA sufficient to allege a false or fraudulent request for payment); *United* States v. Chapman University, No. SACV 04–1245 JVSRCX, 2006 WL 1562231 (C.D.Cal. May 23, 2006) (finding FCA liability where defendant certified they would comply with applicable statutes and regulations, one of which requiring accreditation by a third party entity, and the defendant allegedly obtained the required accreditation through fraud). For the reasons discussed above, the Court finds these district court decisions unpersuasive and unsupported by the language of the FCA and circuit court precedent. Furthermore, such an expansive reading of the FCA would lead to perverse results. For example, under these theories, if a defendant contractor was shown to have engaged in some fraudulent activity in the procurement of its contractor's license from a state licensing board, relators would be able to argue that every subsequent government contract with the federal government and request for payment was "false,"

despite the fact that the alleged fraud was wholly disconnected from the defendant's request for payment.

Relators' argument, if accepted, would also raise substantial policy concerns. Were the FCA construed to allow an FCA claim to be based on misrepresentation and omissions made to the FDA during the FDA approval process, the Court sitting on an FCA case would have to delve deeply into the complexities, subtleties and variabilities of the FDA approval process. Ultimately, to determine materiality under the FCA and the "but-for cause in the chain of causation" analysis advocated by Plaintiff, the Court would have to determine whether the FDA would have in fact approved each drug in question. Given the wide range of administrative responses and action that could have been taken by the FDA (e.g., corrective notices, warnings, plan of remediation, requirement of monitoring), the Court would be tasked not only with determining whether a falsity was presented to the FDA, but also predicting the institutional response of the FDA and the ultimate outcome of a specialized and complex administrative proceeding. Given the range of actions available to the FDA, this would be a daunting task. Cf. U.S. ex rel. Ge v. Takeda Pharm. Co. Ltd., No. 10-11043, 2012 WL 5398564, at \*6 (D.Mass. Nov. 1, 2012) ("[T]he FDA has discretion to take a number of different actions should a drug manufacturer violate the adverse-event reporting requirements. The harshest of those actions is the withdrawal of drug approval. However, the FDA exercises discretion in its enforcement procedures for such types of violations, and does not always prosecute them, let alone enforce the harshest penalty available." (citation omitted)); Zimmerman v. Novartis Pharm. Corp., 889 F.Supp.2d 757, 769 (D.Md. 2012) (noting that the FDA "enforces violations of the drug approval process, not private litigants" and has "a number of enforcement options" including "in rem forfeiture, injunction, and even criminal prosecutions"); see also Cutler v. Hayes, 818 F.2d 879, 893 (D.C.Cir. 1987) ("The FDC Act imposes no clear duty upon FDA to bring enforcement proceedings to effectuate either the safety or the efficacy requirements of the Act."). The Court is ill-equipped to make that kind of prediction. Such an inquiry stands in contrast to the inquiry in a more typical FCA case—determining whether a particular statement or certification made to the payor agency is in fact false and material to the decision to pay. Absent a clear directive from Congress, the Court is unwilling to read into the FCA such an expansive sweep.

2. The Implied Certification and Adulteration / Misbranding Theories of Fraud Do Not State an FCA Claim

Relators also allege that implied misrepresentations were in fact made directly to the CMS in seeking reimbursement. In particular, Relators appear to rely on two similar, but distinct, arguments. First, Relators argue that Gilead impliedly certified to CMS compliance with GMP and safety regulations every time payment for one of the affected drugs was submitted for reimbursement. Second, Relators contend that in selling drugs which under FDA regulations were "adulterated" or "misbranded" drugs, <sup>5</sup> Gilead violated the FCA because the goods sold were not as described.

- A drug can be adulterated for any number of reasons, including contamination in the product; improper controls during manufacturing; or because it differs in strength, quality, or purity from its description in an "official compendium." See generally 21 U.S.C. § 351.
- \*12 As to their implied certification argument, Relators rely in large part on the Ninth Circuit's decision in Ebeid. Unlike Eibed, however, there is no basis for finding any implied certification directed at CMS, the payor agency; payment by CMS was not conditioned on compliance with FDA regulations. All that is required is that the drug in question be approved by the FDA. Relators have cited no Medicare or Medicaid statute, regulation, or contractual term conditioning reimbursement on Gilead's compliance with FDA's safety or GMP regulations.<sup>6</sup> Rather, the only Medicare/Medicaid provision to which Relators cite is the definition of "covered outpatient drug." Under both regimes, a "covered outpatient drug" is, inter alia, one "which is approved for safety and effectiveness as a prescription drug" under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 355 et seq., 42 U.S.C. § 1396r-8 (medicaid); see also id. § 1395w-102(e) (Medicare Part). Here, there is no dispute that the affected drugs at issue in this case were, in fact, "approved" by the FDA.
- Relators have pointed to statements made by Gilead during the FDA approval process in which it certified that it would comply with "all applicable laws" including GMP regulations. For example, at the hearing Relators cited to the 2005 New Drug Application ("NDA") for Gilead's drug "Truvada." At the end of this NDA, as with all NDAs, is a certification box which provides, in relevant part:

I agree to update this application with new safety information about the product that may reasonably

affect the statement of contraindications, warnings, precautions, or adverse reactions in the draft labeling. I agree to submit safety update reports as provided for by regulation or as requested by FDA. if this application is approved, I agree to comply with all applicable laws and regulations that apply to approved applications, including, but not limited to the following:

1. Good manufacturing practice regulations in 21 CFR Parts 210, 211 or applicable regulations, Parts 606, and/or 820.

Docket No. 105–18, at 4 (filed under seal). Relators contend this certification was false when made insofar as the FTC (the active ingredient of Truvada) was not being manufactured pursuant to GMP regulations and was, in fact, adulterated with foreign substances. *See* FAC ¶¶ 105–29. While such statements made during the FDA approval process constitute certifications of regulatory compliance, the certification was not made as part of securing a payment. Relators point to nothing which indicates CMS conditioned payment on such certifications.

In addition, for reasons similar to those discussed above, the implied certification theory is problematic when applied to the pharmaceutical context where Congress has established a complex regulatory regime and an executive agency with broad remedial powers to police and enforce that regime. When an "agency has broad powers to enforce its own regulations, as the FDA does ..., allowing FCA liability based on regulatory non-compliance could 'short-circuit the very remedial process the Government has established to address non-compliance with those regulations." "United States ex rel. Rostholder v. Omnicare, Inc, 745 F.3d 694, 702 (4th Cir. 2014) (quoting United States ex rel. Wilkins v. United Health Group, Inc., 659 F.3d 295, 307 (3d Cir. 2011)). Violations of, for example, cGMPs would seem better addressed by the FDA regulatory process than by the blunt tool of FCA litigation. Thus, in this healthcare context, courts should be cautious before applying the FCA to claims implicating the FDA's oversight and enforcement powers. Cf. Wilkins, 659 F.3d at 307 ("[T]he implied certification theory of liability should not be applied expansively, particularly when advanced on the basis of FCA allegations arising from the Government's payment of claims under federally funded health care programs."); Mikes, 274 F.3d at 699 (noting that the implied certification theory should not be read "expansively and out of context" and "does not fit comfortably into the health care context because the False Claims Act was not designed for use as a blunt instrument to enforce compliance with all medical regulations—but rather only those regulations that are a precondition to payment").

\*13 Similarly, any claim that the drugs sold by Gilead and paid for by CMS were adulterated and hence mislabeled is not cognizable under the FCA in this case. This argument has been squarely addressed—and rejected—by the Fourth Circuit in U.S. ex rel. Rostholder v. Omnicare, Inc., 745 F.3d 694 (4th Cir. 2014). There, the court noted that the Medicare and Medicaid statutes did not require that the sold drugs be unadulterated or misbranded. Rather, the statutes merely defined "covered outpatient drug" (i.e., a drug eligible for reimbursement) as one approved by the FDA. See id. at 701 (noting the statutes provide that a "drug merely must be approved by the FDA"). Thus, reimbursement requests for drugs that, while approved by the FDA, were subsequently "adulterated" or "misbranded" as a result of "having been proceeded in violation of FDA safety regulations" would not give rise to FCA liability. *Id.* The court ultimately concluded:

Here, because compliance with the CGMPs is not required for payment by Medicare and Medicaid, Omnicare has not falsely stated such compliance to the government, as contemplated by the FCA. Thus, relator's allegations of regulatory violations fail to support FCA liability. As we previously have explained, the correction of regulatory problems is a worthy goal, but is "not actionable under the FCA in the absence of actual fraudulent conduct." In the present case, relator has not identified any false statement or other fraudulent misrepresentation that Omnicare made to the government.

Id. at 702.

Omnicare's analysis is persuasive. The FCA is not a "sweeping mechanism to promote regulatory compliance," but rather a "set of statutes aimed at protecting the financial resources of the government from the consequences of fraudulent conduct." Id.; see also Lucky v. Baxter Healthcare Corp., 2 F.Supp.2d 1034, 1045 (N.D.III. 1998) ("[T]he FCA is not a vehicle for regulatory compliance."). Further, the Supreme Court has cautioned that the "False Claims Act was not designed to reach every kind of fraud practiced on the Government." United States v. McNinch, 356 U.S. 595, 599 (1958). FCA liability cannot be based on fraudulent statements made before one regulatory agency and from that implying a certification putatively made to the payor agency where there is neither an express certification nor condition of payment. To do so would transform the FCA into an all-purpose, anti-fraud statute which it is not. United States v. AseraCare Inc., No. 2:12-CV-245-KOB, 2014 WL 6879254, at \*8 (N.D.Ala. Dec. 4, 2014) ("[T]he FCA is not

'an all-purpose antifraud statute.' " (quoting *Allison Engine Co*, 553 U.S. at 672).

To be sure, CMS or the Department of Health and Human Services could require a pharmaceutical manufacturer to certify, for example, its continued adherence to FDA safety and GMP regulations as part of the payment process. *Cf. United States ex rel. Compton v. Midwest Specialties, Inc.*, 142 F.3d 296, 297–98, 304 (6th Cir. 1998) (fraudulent deviation from contractually specified requirements for brake shoes violates the FCA). As the Fourth Circuit held in *Omnicare*, however, that is not the case as alleged, and thus no FCA claim has been stated.

#### 2. Relators Have Failed to Allege a Worthless Services Theory

Relators' final FCA theory is a "worthless services" theory. The Ninth Circuit has noted that in an "appropriate case, knowingly billing for worthless services or recklessly doing so with deliberate ignorance may be actionable under § 3729, regardless of any false certification conduct." *U.S. ex rel. Lee v. SmithKline Beecham, Inc.*, 245 F.3d 1048, 1053 (9th Cir. 2001). The Second Circuit has similarly noted that such a claim is "effectively derivative of an allegation that a claim is factually false because it seeks reimbursement for a service not provided. In a worthless services claim, the performance of the service is so deficient that for all practical purposes it is the equivalent of no performance at all." *Mikes*, 274 F.3d at 703 (citation omitted).

\*14 Courts applying this "factually false" or "worthless services" theory have interpreted it narrowly. Most recently, the Seventh Circuit noted that it is "not enough to offer evidence that the defendant provided services that are worth some amount less than the services paid for. That is, a 'diminished value' of services theory does not satisfy this standard. Services that are 'worth less' are not 'worthless.' " U.S. ex rel. Absher v. Momence Meadows Nursing Center, Inc., 764 F.3d 699, 710 (7th Cir. 2014). That court, therefore, rejected the contention that FCA liability could be based simply on the fact that a good or service had a diminished value or was non-conforming in some respect. See also U.S. ex rel. Ruhe v. Masimo Corp., 977 F.Supp.2d 981, 996 (C.D.Cal. 2013) ("In a worthless services claim involving a medical procedure, the plaintiff must demonstrate that the procedure has 'no medical value.' "). The Seventh Circuit holding is consistent with the worthless services theory articulated by the Ninth Circuit in U.S. ex rel. Lee and the Second Circuit in Mikes.

In the case at bar, Relators allege a variety of deficiencies in Gilead's pharmaceutical products. Some of these allegations touch on the resulting quality of the drug (as opposed to technical or manufacturing related deficiencies). For example:

- Gilead released "lot 904" of FTC, produced at Synthetics
   China prior to it being approved by the FDA, for
   "final drug processing and, ultimately, commercial
   sale" despite the presence of microbial contamination
   —including molds and yeasts beyond established limits
   and two micro-organisms. FAC ¶¶ 57.
- FTC and finished Truvada tablet cores were produced and released for processing that contained the "cyclic FTU" impurity, manifested in the form of charred and degraded particles. Id. ¶¶ 110, 113.
- FTC "Lot 5044" was "both visually contaminated and failed potency and purity testing, but was nevertheless utilized in commercially distributed drug product." *Id.* ¶ 124. Lot 5044 tested at "94.8% potency" when acceptable limited were "98.0102.0%." *Id.* ¶ 125.
- Validation lots from Synthetic China's "Plant 203" were released for commercial sale despite the presence of foreign particles including "blue colored glass, cement and fibrous materials, and metal shards," with the largest piece weighing 39mg—"7.8% by weight of a Truvada tablet, or up to 19.5% of an Emtriva capsule." Id. ¶ 160.
- Validation lots of Viread tablets were released into the commercial market despite the presence of "visible black particles"—eventually discovered to be "teflon, charred TDF, acetaminophen, metal shavings, and other materials"—in numerous batches. *Id.* ¶¶ 180, 184. 185.
- Various products were subject to temperature extremes resulting in "scores of complaints about broken, moist, melted, and/or fused drug products, as well as noticeable odors." *Id.* ¶ 213.

These allegations, and similar allegations throughout the FAC, while troubling, do not establish that the affected lots or products were not only "worth less" or defective, but truly "worthless" for the purposes for which the drugs were designed. *See Momence Meadows*, 764 F.3d at 710. Notably, the United States, in its statement of interest, appears to recognize that the drug at issue would need to be "worthless" in some sense: "Further, in some situations, manufacturing deficiencies violating GMP regulations could

affect the strength, purity, and/or quality of the affected drug such that the drug is essentially 'worthless' and not eligible for payment by the government." Dkt. No. 78, at 3. Here, however, Relators have failed to allege sufficient facts to state a claim under the narrow "worthless services" theory.

The limitations of the "worthless services" doctrine do not prevent an FCA claim for the sale of non-conforming goods to the government where, for example, there is a knowing breach of a material specification established by contract with the payor agency. *See, e.g., Compton* 142 F.3d at 304.

#### 3. Conclusion

\*15 For the foregoing reasons, Relators' FCA claim is dismissed. However, the Court cannot say at this early stage that any amendment by Relators would be futile. Accordingly, Relators will be afforded an opportunity to allege either (1) requests for reimbursement for "worthless services" or (2) an actionable misrepresentation made as part of the payment process consistent with the analysis above. Should Relators seek to file an amended complaint, the Court expects the Relators to organize and streamline the current 747 paragraph, 190 page complaint in light of the above analysis.

### C. Relators' FCA Conspiracy Claim Is Barred by the Intracorporate Conspiracy Doctrine

Relators' third claim for relief asserts a conspiracy to violate the False Claims Act in violation of 31 U.S.C. § 3729(a) (1)(C). This provision creates liability for any person who "conspires to commit a violation" of the FCA. Gilead moves to dismiss this claim, arguing that, as a matter of law, Gilead Alberta ULC and Gilead Sciences, Inc. cannot conspire together because the former is a wholly owned subsidiary of the latter. Docket No. 58, at 25; *see also* Docket No. 57 (Defendants' Certification of Interested Entities) ("Gilead Alberta ULC makes the following disclosure: it is a whollyowned subsidiary of Gilead Alberta LLC, which is a whollyowned subsidiary of Gilead Sciences, Inc.").

Gilead's argument relies on the intra-corporate conspiracy doctrine—an antitrust principle—which "provides that, as a matter of law, a corporation cannot conspire with its own employees or agents." *Hoefer v. Fluor Daniel, Inc.*, 92 F.Supp.2d 1055, 1057 (C.D.Cal. 2000). The reasoning behind this doctrine is that "it is not possible for a single legal entity consisting of the corporation and its agents to conspire with itself, just as it is not possible for an

individual person to conspire with himself." *Microsoft Corp.* v. *Big boy Distribution LLC*, 589 F.Supp.2d 1308, 1322 (S.D.Fla. 2008). Courts have used this principle to bar conspiracy claims where the purported conspirators were a parent corporation and a wholly-owned subsidiary. *See, e.g., United States v. Medco Health Systems, Inc.*, No. 12–522(NLH)(AMD), 2014 WL 4798637, at \*11 (D.N.J. Sept. 26, 2014) ("The intra-corporate conspiracy doctrine, raised by defendants, contemplates the ramifications of this type of parent/subsidiary relationship. The doctrine provides that a wholly owned subsidiary is deemed incapable of conspiring with its parent company, and it has long been applied to conspiracy claims generally.").

Relators contend that this doctrine does not extend beyond the confines of the Sherman Antitrust Act, noting that the Supreme Court has stated that "antitrust law's intracorporate conspiracy doctrine ... turns on specific antitrust objectives." Cedric Kushner Promotions, Ltd. v. King, 533 U.S. 158, 166 (2001). However, courts have not construed the intracorporate conspiracy doctrine as narrowly as Relators contend and a number of courts have applied it in FCA cases. See, e.g., United States ex rel. Chilcott v. KBR, Inc., No. 09cv-4018, 2013 WL 5781660 (C.D.III. Oct. 25, 2013) ("[T]he Court holds that the intracorporate conspiracy doctrine bars FCA conspiracy claims where all the alleged conspirators are either employees or wholly-owned subsidiaries of the same corporation."); United States ex rel. Ruhe v. Masimo Corp., 929 F.Supp.2d 1033, 1038 (C.D.Cal. 2012) ("Contrary to Relators' assertion, this doctrine applies to conspiracy claims outside of antitrust, where it was originally developed, and has in fact been applied by several federal courts to claims under the FCA."); United States ex rel. Fago v. M & T Mortgage Corp., 518 F.Supp.2d 108, 117–18 (D.D.C. 2007) (applying the doctrine in the FCA context). Relators point to no authorities rejecting application of the doctrine in the FCA context.

\*16 Accordingly, in addition to the failure to state a substantive FCA claim, the intracorporate conspiracy doctrine requires that Gilead's motion to dismiss Relators' conspiracy claim under the FCA be **GRANTED**.

#### D. Relators' FCA and FLSA Retaliation Claims

Relators' twenty-eighth and thirty-second causes of action allege that Relator Jeff Campie was retaliated against in violation of the FCA and Fair Labor Standards Act ("FLSA"), respectively. Mr. Campie alleges that beginning "in or about July 2006, and throughout his employment with Gilead,

Relator spoke to Gilead's top executives ... on numerous occasions about concerns he had with and objections to the manufacturing and compliance related practices" alleged in the FAC. FAC ¶ 680. He then contends that Gilead executives engaged in "ongoing retaliation toward him, including, but not limited to, ostracizing Relator Jeff Campie, threatening to terminate his employment in approximately mid-January 2009, and ultimately terminating his employment in July 2009." *Id.* ¶ 681. Mr. Campie asserts that this retaliation was caused by "his opposition and objections to Gilead's unlawful practices." *Id.* ¶ 685.

The FCA contains an anti-retaliation provision which provides:

Any employee ... shall be entitled to all relief necessary to make that employee ... whole, if that employee ... is discharged, demoted, suspended, threatened, harassed, or in any other manner discriminated against in the terms and conditions of employment because of lawful acts done by the employee ... in furtherance of an action under this section or other efforts to stop 1 or more violations of this subchapter.

31 U.S.C. § 3730(h). To state a claim for retaliation under the FCA, a plaintiff must demonstrate: (1) that he or she "engaged in activity protected under the statute"; (2) that the employer knew the plaintiff engaged in protected activity; and (3) the employer discriminated against the plaintiff "because he or she engaged in protected activity." Mendiondo v. Centinela Hosp. Medical Center, 521 F.3d 1097, 1103 (9th Cir. 2008). An employee engages in protected activity by "'investigating matters which are calculated or reasonably could lead to a viable FCA action.' " Moore v. Cal. Institute of Tech. Jet Propulsion Lab., 275 F.3d 838, 845 (9th Cir. 2002) (quoting Anton, 91 F.3d 1269). Protected activity includes situations where: "(1) the employee in good faith believes, and (2) a reasonable employee in the same or similar circumstances might believe, that the employer is possibly committing a fraud against the government." *Moore v. Cal. Institute of Tech.* Jet Propulsion Lab., 275 F.3d 838, 845 (9th Cir. 2002).

#### The FLSA makes it unlawful for an employer to

discharge or in any other manner discriminate any employee because such employee has filed any complaint or caused to be instituted any proceeding under or related to this chapter, or has testified or is about to testify in any such proceeding, or has served or is about to serve on an industry committee; 29 U.S.C. § 215(a)(3). Under this provision, a plaintiff must demonstrate: "(1) the plaintiff must have engaged in statutorily protected conduct under § 5(a)(3) of the FLSA, or the employer must have erroneously believed that the plaintiff engaged in such conduct; (2) the plaintiff must have suffered some adverse employment action; and (3) a causal link must exist between the plaintiff's conduct and the employment action." *Singh v. Jutla & C.D. & R's Oil, Inc.*, 214 F.Supp.2d 1056, 1059 (N.D.Cal. 2012).

\*17 Mr. Campie's retaliation claims fail at this stage for the simple reason that there are insufficient allegations from which it can be inferred that any adverse employment action he suffered was caused by his engaging in protected activity under the FCA or FLSA.<sup>8</sup> Mr. Campie contends that he has sufficiently alleged causation because, in two paragraphs (out of a complaint consisting of 747 paragraphs), he alleged that he "worked for Gilead from 2006 through mid-2009 before his employment was terminated as a result of raising objections to Gilead's conduct." FAC ¶ 5; see also Dkt. No. 84, at 32 ("Finally, Relators have also sufficiently alleged that Mr. Campie suffered adverse action because he engaged in protected conduct." (citing FAC ¶¶ 5, 691)). These are, however, conclusory allegations without any factual support. Similar conclusory allegations regarding causation can be found elsewhere in the FAC. See, e.g., id. ¶ 681 ("On an ongoing basis Relator Jeff Campie raised concerns ... and in response to his having raised such concerns and objections, Caracciolo and Branning, among others at Gilead, engaged in ongoing retaliation toward him....").

Gilead argues that the FAC contains insufficient allegations that Mr. Campie did, in fact, engage in protected conduct. Insofar as Mr. Campie has indicated that he can provide further factual allegations on this point and he will need to amend his retaliation claims for the reason articulated in this order, the Court declines to address this argument until Mr. Campie has had an opportunity to include all pertinent factual allegations in an amended complaint.

These statements fail to provide sufficient *factual* allegations from which it can be inferred that Mr. Campie was subjected to an adverse employment action *because of* his protected activity. *See U.S. ex. rel. Patton v. Shaw Services, LLC*, 418 Fed.Appx. 366, 372 (5th Cir. 2011) ("Patton's allegations that Shaw supervisors retaliated against him for internally reporting 'fraudulent' construction practices ... are conclusory and unsupported by specific facts creating a genuine issue for trial."); *Beers v. Kaiser Permanente* 

Northeast Div., No. 98–CV–1121 (TJM), 1999 WL 1269419, at \*4 (N.D.N.Y. Dec. 16, 1999) ("The alleged temporal proximity between Plaintiff's complaints and termination and Plaintiff's conclusory statements that she was terminated because she complained 'early and often' of violations are insufficient to establish the necessary inference." (citation omitted)). Mr. Campie need not provide extensive factual support on this point. See Mendiondo, 521 F.3d at 1104 ("It suffices at this pleading stage for Mendiondo to simply give notice that she believes CHMC terminated her because of her investigation into the practices she specified in the complaint.").

Here, it appears that Mr. Campie relies on a number of vague allegations and the alleged temporal proximity between his protected conduct and his termination to infer retaliatory intent. For example, he alleges that, at some undisclosed time, he informed Gilead management that it would be "illegal to market" certain drugs from an unregistered facility. FAC ¶ 79. He maintains that he was "rebuked for the warnings by Tony Caracciolo, Gilead's Senior Vice President for Manufacturing and Operations." Id. Similarly, in 2008, when Mr. Campie requested that a customer complaint be sent for analysis he was "critiqued" by his manager and that his manager "reprimanded Mr. Campie for relaying to Gilead management that the commingling incident was a recallable event, stating that this evidenced that Mr. Campie was of little use to the company and that Mr. Campie's 'heart wasn't in the job anymore.' "Id. ¶ 230, 232. Vague allegations of Mr. Campie being "critiqued" at some unspecified date or "reprimanded" a year before his termination are insufficient to give rise to an inference that his termination was the result of protected activity.

Further, in a variety of employment law contexts, courts have been wary about implying causation solely based on temporal proximity where that proximity is not particularly convincing. See, e.g., Vasquez v. County of Los Angeles, 349 F.3d 634, 646 (9th Cir. 2003) (finding no causal link where "the protected activity occurred thirteen months prior to the alleged adverse action" and the plaintiff failed to provide other "evidence of surrounding circumstances that show a retaliatory motive"); Caprio v. Mineta, No. CIVA 04–5805 MLC, 2007 WL 2885815, at \*9 (D.N.J. Sept. 27, 2007) ("Temporal proximity between the protected activity and allegedly retaliatory conduct may be relevant, but hte temporal proximity here is not unusually suggestive, and timing alone is rarely sufficient to establish causation."). Here, the temporal connection is not very strong because Mr. Campie merely alleges that he made

"ongoing complaints" (beginning in July 2006) and that he was eventually terminated in 2009, three years later.

\*18 For the foregoing reasons, Mr. Campie's retaliation claims under the FCA and FLSA will be **DISMISSED** with leave to amend. In his amended complaint, Mr. Campie must allege sufficient factual allegations from which it can be inferred that Gilead terminated him as a result of his protected activity under the FCA and FLSA.

E. The Court Defers Addressing Relators' State Law Claims
Having dismissed Relators' FCA claim and Mr. Campie's
retaliation claims under the FLSA and FCA (the latter with
leave to amend), the only remaining claims are brought under
state law. The Court defers ruling on these claims pending
Relators' amendment to their complaint and proper briefing
on the remaining state law claims.

The Court notes that Gilead moved to dismiss the various state law false claims act causes of action in a five sentence paragraph that failed to cite relevant case law from all of the affected states or otherwise attempted to support its contention that the state law claims should rise or fall with the federal claim. Gilead is advised, for purposes of any further proceeding, that the Court does not consider such a conclusory argument sufficient to actually present a ground for dismissing a cause of action.

#### IV. CONCLUSION

For the foregoing reasons, Relators' federal False Claims Act cause of action is dismissed. As discussed above, Relators will be afforded leave to amend this claim. Further, this dismissal is without prejudice to the United States. *See, e.g., U.S. ex rel. Williams v. Bell Helicopter Textron Inc.*, 417 F.3d 450, 455 (5th Cir. 2005); *U.S. ex rel. Shea v. Verizon Bus. Network Servs. Inc.*, 904 F.Supp.2d 28, 37 (D.D.C. 2012). Mr. Campie's retaliation claims under the FCA and FLSA are also dismissed with leave to amend.

The amended complaint shall be filed by **Monday, February 9, 2015** at **5:00pm**. Insofar as the federal claims in this case remain unsettled, the Court defers consideration of Relators' state law claims.

This order disposes of Docket No. 58.

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IT IS SO ORDERED.

**All Citations** 

Not Reported in Fed. Supp., 2015 WL 106255

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# Tab 7

2019 WL 1370414
Only the Westlaw citation is currently available.
NOT FOR PUBLICATION

United States District Court, D. New Jersey.

Ruth Ann COOPER, D.P.M., individually and as the representative of a class of similarly-situated persons, Plaintiff,

V.

MEDIMETRIKS PHARMACEUTICALS, INC., Defendant.

Civil Action No. 18-11987 (JLL) | | | Signed 03/25/2019

#### **Attorneys and Law Firms**

Matthew Nicholas Fiorovanti, Giordano Halleran & Ciesla PC, Red Bank, NJ, for Plaintiff.

Seth Alan Rafkin, Rafkin Esq, PLLC, Randolph, NJ, for Defendant.

#### **OPINION**

#### JOSE L. LINARES, Chief Judge

- \*1 The plaintiff, Ruth Ann Cooper, D.P.M., brings this putative class action on behalf of herself and all others who are similarly situated against the defendant, Medimetriks Pharmaceuticals, Inc. (hereinafter, "Medimetriks"). (ECF No. 8.) Cooper asserts the following claims for:
- violations of the Junk Fax Prevention Act (hereinafter, "the JFPA"), 47 U.S.C. § 227, concerning faxes that were sent by Medimetriks that failed to provide a notice to recipients of the right to opt out of receiving such faxes and a manner in which to do so, and that were received by those who: (a) had not expressly provided permission to Medimetriks to send such faxes (hereinafter, "the Unsolicited JFPA Claims"), and (b) had expressly provided permission to Medimetriks to send such faxes (hereinafter, "the Sol icited JFPA Claims");
- violations of the New Jersey Junk Fax Act (hereinafter, "the NJJFA"), N.J.S.A. 56:8-157, et seq.;

- violations of the New Jersey Consumer Fraud Act (hereinafter, "the NJCFA"); and
- attorney fees related to each of the aforementioned claims.

For the sake of clarity, the Court notes here that the JFPA sets forth opt-out notice requirements. See 47 U.S.C. § 227(b)(1) –(2). Among other things, the JFPA requires faxed advertisements to contain a notice on the first page that clearly and conspicuously advises that a recipient is legally entitled to opt out from any future faxed advertisements from the sender, and to provide a means to make an opt-out request to that sender. Id. Furthermore, the JFPA provides for a private cause of action. See 47 U.S.C. § 227(b)(3).

Currently pending before the Court is the motion by Medimetriks pursuant to Federal Rule of Civil Procedure (hereinafter, "Rule") 12(b)(6) to dismiss the entire amended complaint. (ECF No. 13 through ECF No. 13-3; ECF No. 19.) In response, Cooper voluntarily withdraws the claims that were brought under the NJCFA, but she otherwise opposes the motion. (ECF No. 18 at 24 (Cooper's withdrawal of the NJCFA claims); *id.* at 8–25 (Cooper's arguments in opposition).)

The Court resolves the motion upon a review of the papers and without oral argument. See L. Civ. R. 78.1(b). For the following reasons, the motion is: (1) granted to the extent that it addresses the Solicited JFPA Claims, the NJJFA Claims, and the claims for attorney fees that are related to the Solicited JFPA Claims and the NJJFA Claims; (2) administratively terminated to the extent that it addresses claims brought under the NJCFA and the claims for attorney fees that are related thereto, because the NJCFA claims have been withdrawn; and (3) denied to the extent that it addresses the Unsolicited JFPA Claims and the claims for attorney fees that are related thereto.

#### I. BACKGROUND

Cooper is a podiatrist who practices in Cincinnati, Ohio. (ECF No. 8 at 3 (the amended complaint alleging that Cooper is a citizen of Ohio); *see also* ECF No. 8-1 at 2–8 (faxes sent by Medimetriks to Cooper that list her office as being located in Cincinnati, Ohio).) Cooper alleges that Medimetriks is a pharmaceutical company that is located in Fairfield, New Jersey, and that specializes in podiatry and dermatology medications. (ECF No. 8 at 3–4.) Cooper further alleges

that Medimetriks "sent facsimile transmissions of unsolicited advertisements ... describ[ing] the commercial availability or quality of [its] products, goods and services" to her office on seven separate occasions between May 2016 and July 2018 "without the required opt-out language." (Id. at 1–2, 4.)

\*2 The faxes contained offers made directly to Cooper for free samples of prescription medications sold by Medimetriks for Cooper to provide to patients. (Id. at 4.) The first two faxes that Cooper received from Medimetriks were in the following format:



(ECF No. 8-1 at 2.) The next five faxes that Cooper received were in this format:

	MEDIMETRIKS PHARMACEUTICALS, INC.	
SAM	PLE REQUEST FORM	
	Rx Only LOPROX*(ciclopirox) Cream, 0.77%  Up to 6 bins of 6 samples each	
Doctor: Ruth Cooper, DPM	Specialty: Podiatry	
Address: 4415-B Altholtz Road	Sulte/Floor: Sulta 200	
City: Cincinnati	State: OH Z/p: 45245	
Phone: 513-943-0400	Fex: 513-943-6115	
State License #: 36.002540	Contact (optional):	
Email (optional):  n compliance with the Prescription Drug Marke bove. Incomplete requests cannot be processe	ting Act (PDMA) regulations, please complete and verify all the Information listed and. Please sign and date this form indicating your request for these samples and fax it	
Email (optional):  n compliance with the Prescription Orug Markis bove. Incomplete requests cannot be processed to Medimetriks Pharmaceuticals, Inc. (973) 882-certify that it am a Ricensed practitioner who can poportunity so works the followability and effec	ting Act (PDMA) regulations, please complete and verify all the Information listed and. Please sign and date this form indicating your request for these samples and fax it	
Email (optional):  n compliance with the Prescription Drug Marke bowe. Incumplate request cannot be processed bowed by the prescription of the pre	rting Act (POMA) regulations, please complete and verify all the information littled at. Flease align and date this form indicating your request for these samples and fax it 500.  Regully prescribe in my state. I am requesting product samples so that I may know the theorems on appropriate patients. I will not self, offer to self, order or better samples.	
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(Id. at 8.)

Cooper alleges that neither she nor anyone on her behalf gave permission to Medimetriks to send her these faxes. (ECF No. 8 at 4.) Furthermore, Cooper alleges that these faxes constituted advertisements under the provisions of the JFPA and the NJJFA. (Id.) In addition, Cooper alleges that the faxes lacked the notice that is required pursuant to the JFPA and NJJFA informing her of the opportunity to opt out of receiving any further faxed advertisements from Medimetriks and providing a manner in which to opt out. (Id. at 12.) Cooper now purports to bring claims on behalf of those who received both solicited and unsolicited faxes from Medimetriks where said faxes lacked the opt-out notice.

#### II. DISCUSSION

#### A. Rule 12(b)(6) Standard

It is not necessary for this Court to restate the standard for resolving this motion to dismiss the amended complaint that has been made pursuant to Rule 12(b)(6), because that standard has already been enunciated. See Palakovic v. Wetzel, 854 F.3d 209, 219-20 (3d Cir. 2017) (setting forth the standard, and explaining the holdings in Bell Atl. Corp. v. Twombly, 550 U.S. 544 (2007), and Ashcroft v. Iqbal, 556 U.S. 662 (2009)); see also Fowler v. UPMC Shodyside, 578 F.3d

203, 209–12 (3d Cir. 2009) (setting forth the standard, and explaining the holdings in *Iqbal* and *Twombly*).

### B. Solicited JFPA Claims and Related Claims For Attorney Fees

Cooper alleges that she did not: (1) give permission to Medimetriks to fax advertisements to her; or (2) solicit such faxed advertisements in any way. (ECF No. 8.) Cooper emphasizes these allegations in opposition to the motion to dismiss. (See ECF No. 18 at 17 (alleging that "Medimetriks repeatedly sent unsolicited facsimiles to Dr. Cooper offering her free samples of Medimetriks' products"); id. at 22 (arguing that "[f]rom a factual standpoint, Dr. Cooper alleged the faxes she received from Medimetriks were unsolicited; i.e., 'without [her] prior express invitation or permission' ").)

As a result, Cooper is unable to proceed as a class representative for those who might have standing to bring the Solicited JFPA Claims, because Cooper is not — in contrast to the caption of the amended complaint — a "similarly-situated person[]" insofar as these particular claims are concerned. (ECF No. 8 at 1.) As correctly argued by Medimetriks, Cooper is unable to represent the interests of the recipients who either solicited or gave permission to Medimetriks to send them faxes, but who then received said faxes without the opt-out information, as Cooper's alleged experiences as to the faxes from Medimetriks were different. (See ECF No. 13-1 at 22-23 (Medimetriks arguing same).) It is well-settled law in the class action context that "[r]epresentatives must be part of the class and possess the *same* interest and suffer the *same* injury as the class members." Amchem Prods., Inc. v. Windsor, 521 U.S. 591, 594-95 (1997) (emphasis added); see also Zimmerman v. HBO Affiliate Grp., 834 F.2d 1163, 1169–70 (3d Cir. 1987) (affirming the dismissal of a cause of action due to the named plaintiff's failure to state a claim, because "to be a class representative on a particular claim, the plaintiff must himself have a cause of action on that claim").

\*3 Furthermore, a named plaintiff in a purported class action cannot conjure up standing by "alleg[ing] a bare procedural violation, divorced from any concrete harm" to him or her, even where "a statute grants a person a statutory right and purports to authorize that person to sue to vindicate that right," unless that plaintiff has alleged an injury-in-fact that is "fairly traceable to the challenged conduct of the defendant." *Spokeo, Inc. v. Robins*, 136 S. Ct. 1540, 1547, 1549 (2016). Even though — as with the situation in the instant case — "a suit may be a class action ... [it] adds nothing to the question of standing, for even named plaintiffs who represent

a class must allege and show that they personally have been injured, not that [an] injury has been suffered by other, unidentified members of the class to which they belong." *Id.* at 1547 n.6 (citations and internal quotes omitted); *see also Ehrheart v. Verizon Wireless*, 609 F.3d 590, 607 (3d Cir. 2010) (holding the same). The Court cannot allow Cooper to proceed as a representative on behalf of those covered by the Solicited JFPA Claims, as Cooper herself neither solicited nor gave permission to receive the faxes from Medimetriks. *See Frank v. Gaos*, No. 17-961, 2019 WL 1264582, at \*3 (U.S. Mar. 20, 2019) (remanding a class action case for further proceedings, because the lower courts failed to determine whether the named plaintiffs had personally experienced the alleged violation at issue, and thus whether those plaintiffs had standing to bring those particular claims).

Therefore, the Solicited JFPA Claims and the claims for attorney fees that are related to the Solicited JFPA Claims are dismissed. However, those claims are dismissed without prejudice, and with leave to Cooper to move for joinder of an additional plaintiff who indeed provided such permission to Medimetriks and then received faxes lacking the required opt-out information pursuant to the JFPA. By granting such leave, the Court is offering no opinion as to whether the Solicited JFPA Claims would then be found to be plausible or meritorious.

### C. Unsolicited JFPA Claims and Related Claims For Attorney Fees

Cooper alleges that she did not permit Medimetriks to send her the faxes, and that the faxes did not contain opt-out information. Thus, the Court finds that Cooper has standing to proceed with the Solicited JFPA Claims. *See Amchem Prods.*, *Inc.*, 521 U.S. at 594–95.

Medimetriks does not deny that the faxes fail to set forth any opt-out language. However, Medimetriks argues that Cooper has not plausibly alleged that the faxes at issue were advertisements, and argues that the faxes offer nothing for sale and were sent to Cooper in her capacity as a podiatrist in order to assist her with patient care. (ECF No. 13-1 at 8, 12.) Medimetriks further argues that "the faxes did not propose any commercial transaction with" Cooper, and thus argues that the JFPA does not apply here. (*Id.* at 8.)

The JFPA defines an "unsolicited advertisement" as "any material advertising the commercial availability or quality of any property, goods, or services which is transmitted to any person without that person's prior express invitation or

permission, in writing or otherwise." 47 U.S.C. § 227(a)(5); see also 47 U.S.C. 227(b)(1) (providing that "[i]t shall be unlawful for any person ... to send, to a telephone facsimile machine, an unsolicited advertisement"). Thus, a fax can still set forth a commercial pretext that falls under the regulation of the JFPA if it is "an indirect commercial solicitation, or pretext for a commercial solicitation." Sandusky Wellness Ctr., LLC v. Medco Health Sols., Inc., 788 F.3d 218, 225 (6th Cir. 2015). All that is required for an unsolicited fax to merit scrutiny under the JFPA is for that fax to "draw[] the relevant market's attention to its product to promote its sale (albeit indirectly)." Id. at 222; see also Physicians Healthsource, Inc. v. Janssen Pharms., Inc., No. 12-2132, 2013 WL 486207, at \*6 (D.N.J. Feb. 6, 2013) (holding insofar as the JFPA is concerned that "publications may be part of an overall marketing campaign to promote the commercial availability and quality of a sender's goods or services," and thus "while the message is informational to the extent that it is notifying the recipient of free ... services, the message can also be construed as [an] advertisement because it contains statements promoting the availability and quality of certain goods or services"). Indeed, as another Federal District Court has held in denying a motion to dismiss by a pharmaceutical-company defendant in a similar case that concerned claims brought under the JFPA, it is certainly plausible in this case that Medimetriks sent the unsolicited faxes to Cooper in her capacity as a podiatrist as advertisements to "promote[] the sale of its products to [her] patients, albeit indirectly, by passing on free samples through [her]," and that "the offer of free products is a vehicle to advertise [the defendant's] products and sell those products to [her] patients." Cooper v. NeilMed Pharms., Inc., No. 16-945, 2017 WL 4349085, at \*4 (S.D. Ohio Sept. 29, 2017).

\*4 As a result, the Unsolicited JFPA Claims will be permitted to go forward, because the Court finds that the faxes at issue may plausibly be considered to be unsolicited advertisements at this juncture. In addition, the claims for attorney fees that are related to the Unsolicited JFPA Claims will also proceed at this juncture, as the Court is utilizing the discretion to refrain from determining the merits of the claims for attorney fees until the Unsolicited JFPA Claims themselves have been resolved on the merits. See Artemi Ltd. v. Safe-Strap Co., Inc., No. 03-3382, 2013 WL 6860734, at \*6 n.7 (D.N.J. Dec. 30, 2013) (denying without prejudice a motion to dismiss claims for attorney fees where the underlying claims in a patent infringement case remained viable, because "decisions concerning entitlement to attorney[] fees can abide the resolution of the merits of th[e] suit").

#### D. NJJFA Claims

Medimetriks argues that Cooper may not proceed in this litigation as the class representative for the claims brought under the NJJFA because she received the faxes in Ohio, and because the NJJFA pertains only to the recipients of fax advertisements within New Jersey. (ECF No. 13-1 at 9.) The NJJFA protects New Jersey residents from being forced to receive unsolicited fax advertisements without being provided with an option to opt out of receiving such faxes. N.J.S.A. 56:8-157; N.J.S.A. 56:8-158(b). Specifically, the NJJFA provides that "[a] person within this State shall not ... send an unsolicited advertisement to a telephone facsimile machine within this State." N.J.S.A. 56:8-158(a).

As discussed earlier by the Court as to the Solicited JFPA Claims, it is well-settled law in the class action context that "[r]epresentatives must be part of the class and possess the same interest and suffer the same injury as the class members." Amchem Prods., Inc., 521 U.S. at 594–95. Cooper is the only named plaintiff in this Action. Cooper is not a New Jersey resident (she is a resident of Ohio) and Cooper did not suffer any alleged injuries in New Jersey (she was allegedly injured in Ohio), and thus Cooper is barred from proceeding as a class representative for the NJJFA claims. See McGuire v. BMW of N. Am., LLC, No. 13-7356, 2014 WL 2566132, at \*6 (D.N.J. June 6, 2014) (in addressing a motion to dismiss putative class action claims, holding that the plaintiff lacked standing to assert claims under the laws of the states in which he did not reside or in which he suffered no injury, because the named plaintiff in a proposed class action should not be permitted to engage in lengthy class discovery for injuries in relation to every state in the country). In fact, Cooper concedes that she does not possess an individual claim under the NJJFA in this action, and that she is uncertain whether anyone in New Jersey even received the subject faxes from Medimetriks. (ECF No. 18 at 23 (Cooper stating that her "faxes were not received in New Jersey," and that she "is seeking to represent all persons who received the ... Faxes some of whom *likely* received these faxes in New Jersey and may ... be entitled to additional remedies under New Jersey law")(emphasis added).)

Therefore, the NJJFA Claims and the claims for attorney fees that are related to the NJJFA Claims are dismissed. However, those claims are dismissed without prejudice, and with leave to Cooper to move for joinder of an additional plaintiff who was allegedly injured by receiving faxes from Medimetriks in violation of the NJJFA within New Jersey.

E. Argument Raised By Medimetriks In The Reply Brief Medimetriks suggests in its reply brief that the Court might consider staying this case at this juncture. (ECF No. 19 at 15–16.) Medimetriks argues that the Court may await the resolution of a matter that is pending in the United States Supreme Court concerning the holding in *Carlton & Harris Chiropractic, Inc. v. PDR Network, LLC*, 883 F.3d 459, 466 (4th Cir. 2018), in which a divided panel of the Fourth Circuit Court of Appeals held that a separate federal statute, *i.e.*, the Hobbs Act, precluded the District Court from considering whether an offer for a free e-book constituted an advertisement under the JFPA. *See PDR Network, LLC v. Carlton & Harris Chiropractic, Inc.*, 139 S. Ct. 478 (2018)

\*5 However, the Court will not rule upon an argument that has been raised in the first instance in a reply brief. *See Alston v. Forsyth*, 379 F. App'x 126, 129 (3d Cir. 2010) (vacating an order granting summary judgment wherein the District Court accepted an argument that was raised for the first time in a reply brief as being dispositive of claims, because there was no meaningful opportunity to present arguments or evidence

(granting a petition for a writ of certiorari).

in opposition to the decisive issue); see also Reap v. Cont'l Cas. Co., 199 F.R.D. 536, 550 n.10 (D.N.J. 2001) (holding that it is improper to raise arguments for the first time in reply papers). If Medimetriks desired the Court to hold this case in abeyance, then it should have sought to do so by a properly-noticed motion that permitted Cooper to either oppose or join in that request.

#### III. CONCLUSION

For the aforementioned reasons: (1) the Solicited JFPA Claims, the NJJFA Claims, and the claims for attorney fees that are related to the Solicited JFPA Claims and the NJJFA Claims are dismissed; (2) the NJCFA claims and the claims for attorney fees that are related thereto are deemed to be withdrawn; and (3) the Unsolicited JFPA Claims and the claims for attorney fees that are related thereto remain viable. An appropriate Order follows this Opinion.

#### **All Citations**

Not Reported in Fed. Supp., 2019 WL 1370414

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# Tab 8

2014 WL 2535221 Only the Westlaw citation is currently available. United States District Court, E.D. North Carolina, Western Division.

Bennie EVANS, Plaintiff,

 $\mathbf{v}$ .

Kenneth RICH, M.D., Capital Neurosurgery, and Anulex Technologies, Inc., Defendants.

> No. 5:13-CV-868-BO. | | Signed June 5, 2014.

#### **Attorneys and Law Firms**

Michael Jacob Anderson, Anderson Law Firm, Wilson, NC, for Plaintiff.

Leslie C. Packer, Ellis & Winters, LLP, Raleigh, NC, Nora F. Sullivan, Ellis & Winters, LLP, Cary, NC, for Defendants.

#### **ORDER**

TERRENCE W. BOYLE, District Judge.

\*1 This cause comes before the Court on defendant Anulex's motion to dismiss and plaintiffs motions to strike and for entry of default, and for leave to file an amended complaint. For the reasons discussed below, plaintiff's motion for leave to file an amended complaint is granted, defendant Anulex's motion to dismiss is granted, and plaintiff's motion to strike and for entry of default is denied.

#### **BACKGROUND**

Plaintiff filed this action in Wilson County Superior Court alleging claims of negligent misrepresentation, fraud, unfair and deceptive trade practices, and breach of the implied warranty of merchantability arising out of back surgery performed on plaintiff by defendant Rich. Plaintiff alleges that Dr. Rich used an "X–Close" suture device, manufactured by Anulex, while performing a microdiscectomy with annular repair on plaintiff on November 15, 2010. Plaintiff further alleges that Annulex, which had obtained approval from the

FDA for use of X-close sutures in soft tissue repair, had not obtained approval from the FDA to use the X-close device in annular repairs and that Dr. Rich did not obtain permission from plaintiff to participate in the investigation of the use of the X-close device in his annular repair.

Anulex removed plaintiff's action to this Court on December 20, 2013, pursuant to the Court's federal question jurisdiction. 28 U.S. C. §§ 1441; 1331. At the time of Anulex's removal, service had not been effected on the remaining defendants. 28 U.S.C. § 1446(b)(2). Anulex then filed the instant motion to dismiss for failure to state a claim upon which relief can be granted pursuant to Rule 12(b)(6) of the Federal Rules of Civil Procedure. Plaintiff did not respond to the motion to dismiss. Plaintiff filed a motion to strike Anulex's motion to dismiss and for entry of default pursuant to Rule 55(a) of the Federal Rules of Civil Procedure against Anulex. Plaintiff then moved to amend his complaint, filing a proposed amended complaint in support of his motion almost one month later.

#### **DISCUSSION**

I. Motion for Leave to File Amended Complaint The Court begins its analysis with plaintiff's motion for leave to file an amended complaint. Rule 15 of the Federal Rules of Civil Procedure provides that a party may amend his pleadings as a matter of right under certain circumstances or with the opposing party's consent or leave of court. Fed.R.Civ.P. 15(a)(1)-(2). Further, Rule 15 directs that leave to amend should be freely given when justice so requires. Fed.R.Civ.P. 15(a)(2). "This liberal rule gives effect to the federal policy in favor of resolving cases on their merits instead of disposing of them on technicalities." Laber v. Harvey, 438 F.3d 404, 426 (4th Cir. 2006). A court should only deny leave to amend a pleading when the amendment would be prejudicial to the opposing party, where there has been bad faith on the part of the moving party, or when the amendment would be futile. Johnson v. Oroweat Foods Co., 785 F.2d 503, 509 (4th Cir.1986) (citing Foman v. Davis, 371 U.S. 178, 182 (1962).

\*2 The Court finds no prejudice in allowing plaintiff to amend his complaint nor does it find any bad faith present. Because the Court will consider Anulex's motion to dismiss as addressed to plaintiff's amended complaint, it declines to consider here whether the proposed amendment is futile. According, plaintiff's motion for leave to file an amended complaint is GRANTED. The clerk is DIRECTED to correct

the Court's docket to reflect that the amended complaint filed at docket entry twenty-one is "proposed" and is further directed to file the amended complaint as of the date of entry of this order.

#### II. Motion to Dismiss

Although the Court has allowed plaintiff to file an amended complaint, it may consider Anulex's motion to dismiss as it relates to the remaining count raised against it in plaintiff's amended complaint. See 6 Charles A. Wright, Arthur R. Miller, and Mary Kay Kane, Federal Practice and Procedure § 1476 (3d ed.1998) ("defendants should not be required to file a new motion to dismiss simply because an amended pleading was introduced while their motion was pending."). Plaintiff's only claim in his amended complaint against Anulex is one for unfair and deceptive trade practices under N.C. Gen.Stat. § 75–1.1. As argued in Anulex's motion to dismiss, however, such claim is impliedly preempted under Buckman Company v. Plaintiff's Legal Committee, 531 U.S. 341 (2001).

There is no private right of action under the Food, Drug, and Cosmetic Act (FDCA), as amended by the Medical Device Act (MDA). *Id.* at 352. Thus, where private litigants are effectively suing for a violation of the FDCA under the guise of state law, their claims are impliedly preempted. Loreto v. Proctor & Gamble Co., 515 Fed. App'x 576, 579 (6th Cir.2013) (citation omitted). The test for determining whether a state law claim is impliedly preempted is whether or not the claim would exist in the absence of the FDCA. Id. Though there is a narrow class of state law claims which may survive Buckman preemption, Riley v. Cordis Corp., 625 F.Supp.2d 769, 777 (D.Minn.2009), *Buckman* has been applied in particular contexts to impliedly preempt such state law claims as breach of warranty, negligence per se, design defect, and failure to warn. In re Medtronic, Inc. Sprint Fidelis Leads Products Liab. Litig., 592 F.Supp.2d 1147, 1159-64 (D.Minn.2009).

In his amended complaint, plaintiff alleges that Anulex conspired with physicians to use X-close sutures in annular repairs where patients had excellent prognoses for recovery in order to "stockpile" positive outcome cases so that it might gain FDA approval for use of X-close devices in annular repairs. At bottom, plaintiff seeks to hold Anulex liable for off-label promotion of its X-close suture device, but such claim is impliedly preempted as it exists solely by virtue of the requirements of the FDCA. *Buckman*, 531 U.S. at 353; see also In re Epogen & Aranesp Off-Label Mktg. & Sales Practices Litig., 590 F.Supp.2d 1282, 190–91

(C.D.Cal.2008) (off-label promotion violates the FDCA but the FDCA provides for no private right of action; nor can plaintiffs use "state unfair competition laws as a vehicle to bring a private cause of action that is based on violations of the FDCA.").

\*3 Even if the Court were to assume arguendo that plaintiff's UDTPA claim was not impliedly preempted by Buckman, plaintiff has failed to state a plausible claim for relief. "To prevail on a claim of unfair and deceptive trade practices, a plaintiff must show: (1) defendants committed an unfair or deceptive act or practice; (2) in or affecting commerce; and (3) that plaintiff was injured thereby." First Atl. Mgmt. Corp. v. Dunlea Realty Co., 131 N.C.App. 242, 252 (1998). A trade practice is unfair if it is immoral, unethical, oppressive, or substantially injurious. Id. (citation omitted). Plaintiff has alleged no facts that would support that any actions taken by Anulex would rise to the level of an unfair trade practice as that term is defined by North Carolina law. Thus, plaintiff's sole claim against Anulex must be dismissed.

#### III. Motion to Strike and for Entry of Default

Plaintiff's motion to strike Anulex's motion to dismiss and for entry of default is denied. Anulex's motion to dismiss was filed within the time allowed by the clerk's order granting Anulex's motion to extend time to respond to plaintiff's complaint. Entry of default under Rule 55(a) of the Federal Rules of Civil Procedure is therefore inappropriate. Plaintiff's request that the motion to dismiss be stricken is improper and without merit. The motion is therefore denied.

#### **CONCLUSION**

For the foregoing reasons, plaintiff's motion to amend complaint [DE 18] is GRANTED and the clerk is DIRECTED to file plaintiff's amended complaint [DE 21] as of the date of entry of this order. The clerk is further DIRECTED to correct docket entry twenty-one to reflect that the amended complaint filed by plaintiff was "proposed ." Plaintiff's motion for extension of time to file a memorandum of law [DE 19] is DENIED AS MOOT. Defendant Anulex's motion to dismiss [DE 9] is GRANTED and Anulex is DISMISSED from this action. Plaintiff's motion to strike and for entry of default [DE 15] is DENIED.

SO ORDERED,

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2014 WL 2535221

**All Citations** 

Not Reported in F.Supp.3d, 2014 WL 2535221

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## Tab 9

486 F.Supp.3d 1001 United States District Court, W.D. North Carolina, Asheville Division.

> EXELA PHARMA SCIENCES, LLC, Plaintiff,

> > v.

SANDOZ, INC., Defendant.

CIVIL CASE NO. 1:19-cv-00318-MR | Signed 09/15/2020

#### **Synopsis**

**Background:** Pharmaceutical developer and manufacturer, which produced product for injecting particular amino acid, brought action against second company, which imported and sold non-FDA approved product containing same amino acid, asserting claims for unfair and deceptive trade practices, tortious interference with prospective business advantage, false advertising, and unfair competition. Manufacturer moved for preliminary injunction requiring importing company to recall, recover, remove from interstate commerce, and cease sale of, its product. Importing company moved to dismiss.

**Holdings:** The District Court, Martin Reidinger, Chief Judge, held that:

- [1] manufacturer's claim, under North Carolina Unfair and Deceptive Trade Practices Act (UDTPA), that Food and Drug Administration (FDA) acted unlawfully by permitting second company to import and sell its non-approved product, was preempted under FDCA;
- [2] manufacturer's claim that second company violated UDTPA by failing to update "Dear Healthcare Provider" letter to inform customers that manufacturer had received FDA approval on its product was preempted under FDCA;
- [3] manufacturer's claim that second company violated UDTPA by failing to warn customers that its product failed to meet same aluminum content-level requirements required of pharmaceutical manufacturer's product for FDA approval was preempted under FDCA;

- [4] manufacturer's claim that second company tortiously interfered with manufacturer's prospective economic advantage by introducing unapproved drug into interstate commerce was preempted under FDCA;
- [5] manufacturer failed to allege that second company was not motivated by legitimate business purpose in importing and selling its product, as necessary to state claim that second company tortiously interfered with manufacturer's prospective economic advantage by introducing unapproved drug into interstate commerce;
- [6] manufacturer's claim that second company violated Lanham Act by continuing to send "Dear Healthcare Provider" letter stating that there were no FDA approved injection products with amino acid in question after manufacturer's product received FDA approval was precluded by FDCA; and
- [7] manufacturer failed to allege that second company made any statement that would be rendered false or misleading by failing to affirmatively provide information regarding its product's aluminum content or aluminum content of manufacturer's product, as necessary to state claim that second company's failure to disclose such information violated Lanham Act.

Motion to dismiss granted; motion for preliminary injunction denied.

West Headnotes (32)

### [1] Federal Civil Procedure - Information and belief

Conclusory allegations in a complaint based "upon information and belief" are no substitute for plausible factual allegations that wrongdoing has occurred.

[2] Federal Civil Procedure Matters considered in general

Federal Civil Procedure 🕪 Motion

A district court may consider a document submitted by a defendant without converting a motion to dismiss for failure to state a claim

to a summary judgment motion if the document was integral to and explicitly relied on in the complaint and if the plaintiffs do not challenge its authenticity. Fed. R. Civ. P. 12(b)(6).

### [3] Federal Civil Procedure - Insufficiency in general

For a complaint to be plausible on its face, as necessary to survive a motion to dismiss for failure to state a claim, a plaintiff must demonstrate more than a sheer possibility that a defendant has acted unlawfully. Fed. R. Civ. P. 12(b)(6).

# [4] Federal Civil Procedure Matters deemed admitted; acceptance as true of allegations in complaint

In reviewing a complaint on motion to dismiss for failure to state a claim, the court must accept the truthfulness of all factual allegations but is not required to assume the truth of bare legal conclusions. Fed. R. Civ. P. 12(b)(6).

### [5] Federal Civil Procedure - Insufficiency in general

On review of a motion to dismiss for failure to state a claim, determining whether a complaint states a plausible claim for relief is a context-specific task which requires the court to assess whether the factual allegations of the complaint are sufficient to raise the right to relief above the speculative level. Fed. R. Civ. P. 12(b)(6).

### [6] Federal Civil Procedure - Insufficiency in general

To satisfy plausibility standard required to survive a motion to dismiss for failure to state a claim, a plaintiff need not forecast evidence sufficient to prove the elements of the claim; however, the complaint must allege sufficient facts to establish those elements. Fed. R. Civ. P. 12(b)(6).

### [7] Federal Civil Procedure - Insufficiency in general

To satisfy plausibility standard required to survive a motion to dismiss for failure to state a claim, while a plaintiff does not need to demonstrate in a complaint that the right to relief is probable, the complaint must advance the plaintiff's claim across the line from conceivable to plausible. Fed. R. Civ. P. 12(b)(6).

### [8] States • Conflicting or conforming laws or regulations

Under the Supremacy Clause, state laws that conflict with federal law are without effect. U.S. Const. art. 6, § 2.

### [9] States • Conflicting or conforming laws or regulations

Conflict preemption exists where there is an actual conflict between state and federal law and the state law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress. U.S. Const. art. 6, § 2.

#### [10] States 🐎 State police power

In evaluating whether federal law has preempted state law, a court must look to the purpose of Congress as the ultimate touchstone, while also starting with the assumption that the historic police powers of the states were not to be superseded unless that was the clear and manifest purpose of Congress. U.S. Const. art. 6, § 2.

### [11] Health Administrative proceedings and rulemaking

The FDCA gives the Food and Drug Administration (FDA) complete discretion to decide how and when its enforcement authority should be exercised. Federal Food, Drug, and Cosmetic Act, § 1 et seq., 21 U.S.C.A. § 301 et seq.

[12] Action • Statutory rights of action

**Health** ightharpoonup Judicial review or intervention

Private litigants may not bring a state-law claim against a defendant when the state-law claim is in substance, even if not in form, a claim for violating the FDCA. Federal Food, Drug, and Cosmetic Act, § 1 et seq., 21 U.S.C.A. § 301 et seq.

[13] Action 🌭 Statutory rights of action

**Health**  $\leftarrow$  Judicial review or intervention

There can be no state law cause of action if a plaintiff's true goal is to privately enforce alleged violations of the FDCA. Federal Food, Drug, and Cosmetic Act, § 1 et seq., 21 U.S.C.A. § 301 et seq.

[14] Health 🕪 Preemption

**States** Product safety; food and drug laws

The test for determining whether a state law claim is impliedly preempted by the FDCA is whether or not the claim would exist in the absence of the FDCA. Federal Food, Drug, and Cosmetic Act, § 1 et seq., 21 U.S.C.A. § 301 et seq.

[15] Health  $\leftarrow$  Preemption

**States** Product safety; food and drug laws

Any state law claim that relies on the FDCA or its implementing regulations as a critical element is impliedly preempted. Federal Food, Drug, and Cosmetic Act, § 310(a), 21 U.S.C.A. § 337(a).

[16] Health • Preemption

**States** Product safety; food and drug laws

A state-law claim that a defendant made misrepresentations to the FDA is preempted by the FDCA because such a claim would not exist absent the federal regulatory scheme established by the FDCA. Federal Food, Drug, and Cosmetic Act, § 1 et seq., 21 U.S.C.A. § 301 et seq.

[17] Antitrust and Trade Regulation Fraud; deceit; knowledge and intent

An act is "deceptive," within the meaning of the North Carolina Unfair and Deceptive Trade Practices Act (UDTPA), if it has a tendency or capacity to deceive. N.C. Gen. Stat. Ann. § 75-1.1.

[18] Antitrust and Trade Regulation • In general; unfairness

An act is "unfair," within the meaning of the North Carolina Unfair and Deceptive Trade Practices Act (UDTPA), if it offends established public policy, is immoral, unethical, oppressive, unscrupulous, or substantially injurious to consumers, or amounts to an inequitable assertion of power or position. N.C. Gen. Stat. Ann. § 75-1.1.

[19] Antitrust and Trade Regulation • In general; unfairness

Antitrust and Trade Regulation Public impact or interest; private or internal transactions

What is an unfair or deceptive trade practice, within the meaning of the North Carolina Unfair and Deceptive Trade Practices Act (UDTPA), usually depends upon the facts of each case and the impact the practice has in the marketplace. N.C. Gen. Stat. Ann. § 75-1.1.

[20] Antitrust and Trade

Regulation Preemption

States 🐎 Trade Regulation; Monopolies

Pharmaceutical developer and manufacturer's claim under North Carolina Unfair and Deceptive Trade Practices Act (UDTPA), that Food and Drug Administration (FDA) acted unlawfully by permitting second company, which created non-FDA approved product

containing same amino acid as product created by pharmaceutical manufacturer, to import and sell its non-approved product, was preempted under FDCA; FDCA gave FDA complete discretion to decide whether to bring enforcement proceedings, FDA had approved import and sale of second company's product to meet critical shortage of amino acid in question, crux of pharmaceutical manufacturer's claim was challenge under FDCA, which did not create private right of action, and claim would stand as obstacle to FDCA empowering FDA to combat drug shortages. Federal Food, Drug, and Cosmetic Act, § 1 et seq., 21 U.S.C.A. § 301 et seq.; N.C. Gen. Stat. Ann. § 75-1.1.

#### [21] Health • New drugs

The Food and Drug Administration (FDA) has power under the FDCA to determine whether particular drugs require an approved New Drug Application (NDA) in order to be sold to the public. Federal Food, Drug, and Cosmetic Act, § 1 et seq., 21 U.S.C.A. § 301 et seq.

#### [22] Antitrust and Trade

**Regulation** > Preemption

#### States - Trade Regulation; Monopolies

Pharmaceutical developer and manufacturer's claim that second company, which created product, not approved by Food and Drug Administration (FDA), containing same amino acid as product created by pharmaceutical manufacturer, violated North Carolina Unfair and Deceptive Trade Practices Act (UDTPA) by failing to update "Dear Healthcare Provider" letter to inform customers that pharmaceutical manufacturer had received FDA approval on its product, was preempted under FDCA; FDCA prohibited private action to enforce FDA regulation of products, FDA controlled contents of Dear Healthcare Provider letters, and second company could not unilaterally update those letters without FDA involvement and approval, which was not matter of state-law concern. Federal Food, Drug, and Cosmetic Act, § 1 et seq., 21 U.S.C.A. § 301 et seq.; N.C. Gen. Stat. Ann. § 75-1.1.

#### [23] Antitrust and Trade

**Regulation** > Preemption

States 🐎 Trade Regulation; Monopolies

Pharmaceutical developer and manufacturer's claim that second company, which created product, not approved by Food and Drug Administration (FDA), containing same amino acid as product created by pharmaceutical manufacturer, violated North Carolina Unfair and Deceptive Trade Practices Act (UDTPA) by failing to warn customers that its product failed to meet same aluminum contentlevel requirements required of pharmaceutical manufacturer's product for FDA approval, was preempted under FDCA; crux of pharmaceutical manufacturer's claim was against FDA, for temporarily permitting importation and sale of product that did not meet same aluminum levels FDA required manufacturer's product to meet for permanent approval, and FDCA did not create private right of action that would permit such a claim. Federal Food, Drug, and Cosmetic Act, § 1 et seq., 21 U.S.C.A. § 301 et seq.; N.C. Gen. Stat. Ann. § 75-1.1.

### [24] States Particular cases, preemption or supersession

#### **Torts** > Preemption

Pharmaceutical developer and manufacturer's claim that second company, which created product, not approved by Food and Drug Administration (FDA), containing same amino acid as product created by pharmaceutical manufacturer, tortiously interfered manufacturer's prospective economic advantage by introducing unapproved drug into interstate commerce, was preempted under FDCA; FDA gave second company temporary permission to import and sell drug, and, as FDCA created no private right of action, FDA was only entity that could bring claim against second company for alleged introduction of illegal product into interstate commerce. Federal Food, Drug, and

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Cosmetic Act, § 1 et seq., 21 U.S.C.A. § 301 et seq.

### [25] Torts ← Prospective advantage, contract or relations; expectancy

Under North Carolina law, tortious interference with prospective economic advantage arises when a party interferes with a business relationship by maliciously inducing a person not to enter into a contract with a third person, which he would have entered into but for the interference, if damage proximately ensues, when this interference is done not in the legitimate exercise of the interfering person's rights.

### [26] Torts ← Defense, justification or privilege in general

Under North Carolina law, for purposes of a claim of tortious interference with prospective economic advantage, because the interference must be done outside of the legitimate exercise of the interfering person's rights, interference with a contract is justified if it is motivated by a legitimate business purpose, as when the plaintiff and the defendant are competitors.

#### [27] Torts • Knowledge and intent; malice

Under North Carolina law, to survive dismissal, a complaint alleging tortious interference with prospective economic advantage must admit of no motive for interference other than malice.

### [28] Torts Physicians and health care; health insurance

Under North Carolina law, pharmaceutical developer and manufacturer failed to allege that second company, which created product, not approved by Food and Drug Administration (FDA), containing same amino acid as product created by pharmaceutical manufacturer, was not motivated by legitimate business purpose in importing and selling its product, as necessary to state claim that second company tortiously

interfered with manufacturer's prospective economic advantage by introducing unapproved drug into interstate commerce; manufacturer's own allegations were that second company schemed to "compete" in market for amino acid in question.

### [29] Antitrust and Trade Regulation Advertising, Marketing, and

To state a claim for false advertising under the Lanham Act, a plaintiff must allege that: (1) the defendant made a false or misleading description of fact or representation of fact in a commercial advertisement; (2) the misrepresentation is material, in that it is likely to influence the purchasing decision; (3) the misrepresentation actually deceives or has the tendency to deceive a substantial segment of its audience; (4) the defendant placed the false or misleading statement in interstate commerce; and (5) the plaintiff has been or is likely to be injured as a result of the misrepresentation, either by direct diversion of sales or by a lessening of goodwill associated with their product. Lanham Trade-Mark Act, § 1 et seq., 15 U.S.C.A. § 1051 et seq.

#### [30] Antitrust and Trade

**Regulation**  $\leftarrow$  Omissions and other failures to act in general; disclosure

Unless the omission of a statement would render an affirmative statement false or misleading, the Lanham Act imposes no affirmative duty of disclosure. Lanham Trade-Mark Act, § 1 et seq., 15 U.S.C.A. § 1051 et seq.

# [31] Antitrust and Trade Regulation Exclusive and concurrent remedies

Pharmaceutical developer and manufacturer's claim that second company, which created product, not approved by Food and Drug Administration (FDA), containing same amino acid as product created by pharmaceutical manufacturer, violated Lanham Act by

continuing to send "Dear Healthcare Provider" letter stating that there were no FDA approved injection products with amino acid in question after manufacturer's product received FDA approval, was precluded by FDCA; letters were condition of FDA's approval of second company's import and sale of its product, and had been preapproved by FDA, and FDCA prohibited private action to enforce FDA regulation of products. Lanham Trade-Mark Act, § 1 et seq., 15 U.S.C.A. § 1051 et seq.; Federal Food, Drug, and Cosmetic Act § 1, 21 U.S.C.A. § 301 et seq.

### [32] Antitrust and Trade Regulation Particular cases

Pharmaceutical developer and manufacturer failed to allege that second company, which created product, not approved by Food and Drug Administration (FDA), containing same amino acid as product created by pharmaceutical manufacturer, made any statement that would be rendered false or misleading by failing to affirmatively provide information regarding its product's aluminum content or aluminum content of manufacturer's product, as necessary to state claim that second company's failure to disclose such information violated Lanham Act. Lanham Trade-Mark Act, § 1 et seq., 15 U.S.C.A. § 1051 et seq.

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#### MEMORANDUM OF DECISION AND ORDER

MARTIN REIDINGER, Chief United States District Judge

\*\*1 \*1007 THIS MATTER comes before the Court upon the Plaintiff's Motion for *Ex Parte* Temporary Restraining Order and Preliminary Injunction [Doc. 3], and the Defendant's Motion to Dismiss the Complaint or, in the Alternative, Stay the Case Pending Referral to FDA [Doc. 29].

#### I. PROCEDURAL BACKGROUND

On November 6, 2019, Exela Pharma Sciences, LLC, (the "Plaintiff"), initiated this action against Sandoz, Inc., (the "Defendant"), asserting claims for unfair and deceptive trade practices in violation of N.C. Gen. Stat. 75-1.1, et seq. ("Chapter 75"); tortious interference with prospective business advantage in violation of North Carolina common law; and false advertising and unfair competition in violation of the Lanham Act, 15 U.S.C. § 1125(a). [Doc. 1]. Along with the Complaint, the Plaintiff filed a motion seeking the immediate issuance of a temporary restraining order and a preliminary injunction requiring the Defendant to recall and take all necessary steps to recover, remove from interstate commerce, and cease the sale of all the Defendant's L-Cysteine product. [Doc. 3]. In support of its motion, the Plaintiff relies upon the allegations of its Complaint, as verified by the Plaintiff's manager, Phanesh Koneru, <sup>1</sup> as well as several exhibits.

Mr. Koneru's Verification provides as follows: "That he/she has read the foregoing COMPLAINT; that he/she is the Manager of Exela Pharma Sciences LLC, named Plaintiff in this matter, and that he/she know the contents thereof; that the same is true of his/her own knowledge, except as to those matters and things stated therein upon information and belief, and as to those matters and things he/she believes them to be true." [Doc. 1 at 29 (emphasis added)].

The Court held a hearing on the Plaintiff's request for a temporary restraining order on November 7, 2019. On November 12, 2019, the Court issued an Order denying the Plaintiff's request for a temporary restraining order, finding that the Plaintiff failed to show "its entitlement to such relief." [Doc. 16 at 9]. Nevertheless, the Court held the Plaintiff's request for a preliminary injunction in abeyance

pending further presentation of evidence and briefing by the parties. [Id. at 13].

On December 6, 2019, the Defendant filed a Response in Opposition to Plaintiff's Motion for Preliminary Injunction [Doc. 31] and a Motion to Dismiss the Complaint or, in the Alternative, Stay the Case Pending Referral to FDA [Doc. 29]. On December 13, 2019, the Plaintiff filed a Reply in Support of Plaintiff's Motion for Preliminary Injunction [Doc. 33]. On December 23, 2019, the Plaintiff filed a Response in Opposition to Defendant's Motion to Dismiss. [Doc. 38].

Having been fully briefed, this matter is ripe for disposition.

#### II. FACTUAL BACKGROUND

- [1] The Plaintiff's Verified Complaint presents the following facts.<sup>2</sup>
- Several allegations in the Complaint are made "on information and belief." Mr. Koneru did not verify such statements (see footnote 1 *supra*), and the Plaintiff provided no affidavits or sworn testimony to support such allegations at the hearing. Conclusory allegations based "upon information and belief" are no substitute for plausible factual allegations that wrongdoing has occurred. See Harman v. Unisys Corp., 356 F. App'x 638, 640 (4th Cir. 2009) (stating that allegations that included the phrase "upon information and belief" were insufficient to defeat a motion to dismiss because the allegations at issue were "conclusory"). As such, the conclusory allegations in the Complaint that are made "on information and belief" will not be considered.
- \*\*2 \*1008 The Plaintiff is a North Carolina limited liability company with its principal place of business in Lenoir, North Carolina.<sup>3</sup> [Doc. 1 at ¶ 14]. The Plaintiff develops, manufactures, and markets injectable pharmaceutical products, including an L-Cysteine injection product that is now approved by the FDA. [Id. at ¶¶ 14, 42-43].
- The Plaintiff asserts subject matter jurisdiction in this Court pursuant to the existence of diversity jurisdiction per 28 U.S.C. § 1332 and federal question jurisdiction based on the Lanham Act claim. See 28 U.S.C. § 1331, 15 U.S.C. § 1125(a). The Plaintiff has not presented sufficient allegations to invoke diversity jurisdiction. Nevertheless, the Court will address the Motion to

Dismiss based on the existence of federal question jurisdiction.

L-Cysteine is an amino acid that is administered by parenteral administration (i.e., injection or intravenous infusion) to high-risk patients, such as preterm or low-weight newborns and patients with severe liver disease, as part of a nutritional supplement regimen (also known as "total parenteral nutrition" or "TPN"). [Id. at ¶ 26]. Aluminum is a known contaminant of TPN solutions, and aluminum toxicity can cause serious health problems including dementia and impaired neurologic development among others. [Id. at ¶ 27]. High-risk infants who receive TPN are particularly susceptible to harm from excessive, toxic amounts of aluminum, as they have immature kidneys, which impairs the removal of aluminum from the body. [Id. at ¶ 28]. The Defendant manufactures an L-Cysteine product in Canada with a label stating that it contains as much as 5,000 mcg/L of aluminum. [Id. at ¶ 5]. The Defendant's L-Cysteine product is not approved by the FDA. [Id. at ¶ 1].

[2] Beginning in 2014, there was a shortage of L-Cysteine in the United States. 4 [Docs. 1-15, 31-2 at 2]. This led the FDA to approach the Defendant about importing and selling its unapproved L-Cysteine product in the United States under the FDA's "shortage program" without requiring the drug to obtain FDA approval. [Id.; Doc. 1 at ¶¶ 6, 38]. Pursuant to the shortage program and the Defendant's request, the FDA ultimately gave the Defendant a "Memorandum of Discretion" on April 12, 2016 [Doc. 31-2 at 38-39], which stated that the FDA would not bring an enforcement action against the Defendant for importing and selling its L-Cysteine product for 6 months if the Defendant followed certain conditions. [Id. at ¶ 40, 44; see also Doc. 31-2 at 6, 13-16, 38-39, 41-59]. One such condition was that the Defendant \*1009 had to distribute a "Dear Healthcare Provider" letter alongside its L-Cysteine product that explained the product, the drug shortage, and the lack of other similar FDA-approved products. [Doc. 1 at ¶ 41; Doc. 1-17; Doc. 1-18; see also Doc. 31-2 at 41-59]. The contents of the letters were pre-approved by the FDA and those letters had to be reviewed by the FDA before distribution. [Doc. 31-2 at 41-50].

- Discussions between the FDA and the Defendant regarding the shortage began in 2014. [Doc. 31-2 at 2].
- The Plaintiff's Complaint does not attach the Memorandum of Discretion or the communications between the FDA and the Defendant related to the issuance of the Memorandum of Discretion and

its subsequent renewals. The Defendant, however, attaches the Memorandum of Discretion and those communications to its Response in Opposition to Plaintiff's Motion for Preliminary Injunction. [Doc. 31-2 at 13-16, 38-39, 41-59]. The Court may consider a document submitted by a defendant without converting a Rule 12(b)(6) motion to a summary judgment motion if the document "was integral to and explicitly relied on in the complaint and if the plaintiffs do not challenge its authenticity." Am. Chiropractic Ass'n v. Trigon Healthcare, Inc., 367 F.3d 212, 234 (4th Cir. 2004) (citation and quotations omitted); see also Lee v. City of Los Angeles, 250 F.3d 668, 688 (9th Cir. 2001). The Memorandum of Discretion and the communications surrounding its issuance and renewals are integral documents that were explicitly referenced and relied upon in the Plaintiff's complaint. [Doc. 1]. The Plaintiff does not challenge the authenticity of those documents. As such, the Court will consider the contents of the Memorandum of Discretion and the communications between the FDA and the Defendant when analyzing this Motion. [Doc. 31-2 at 13-16, 38-39, 41-59].

\*\*3 The Defendant sought several extensions of the Memorandum of Discretion and the FDA granted each of the Defendant's requests, with each renewal providing the Defendant with six additional months to import and distribute its unapproved product. [Doc. 1 at ¶ 40]. The FDA approved the last Dear Healthcare Provider letter on June 21, 2019, instructing the Defendant to ensure that the "previously reviewed Dear Healthcare Provider letter continues to accompany [the Defendant's] L-Cysteine in distribution" in shipments thereafter. [Doc. 31-2 at 50]. Every version of the letter stated that "there are currently no FDA-approved L-Cysteine Hydrochloride Injection products in the United States." [Doc. 1 at ¶ 41; Doc. 1-18; see also Doc. 31-2 at 41-59].

Beginning in 2017, the Plaintiff undertook extensive efforts to tackle the aluminum problem in TPN solutions and develop an L-Cysteine product with low aluminum levels. [Doc. 1 at ¶ 31]. In May 2017, the Plaintiff filed a New Drug Application (NDA) with the FDA for an L-Cysteine product that contained a maximum of 1,400 mcg/L of aluminum. [Id.]. In July 2017, however, the FDA informed the Plaintiff that this proposed level of aluminum was unacceptably high, and that the product should have less than or equal to 145 mcg/L of aluminum in order to gain permanent approval. [Id. at ¶ 32]. The Plaintiff ultimately succeeded in reducing the aluminum levels in its L-Cysteine product to less than 120 mcg/L and submitted its new data to the FDA for its redeveloped product in July 2018. [Id. at ¶ 33]. On April 16,

2019, the FDA approved the Plaintiff's NDA under Fast Track designation and Priority Review. [<u>Id.</u>]. The Plaintiff branded its L-Cysteine product ELCYS. [<u>Id.</u>].

After ELCYS received FDA approval, the Plaintiff's marketing and sales teams began communicating with health systems regarding its availability. [Id. at ¶ 34]. By late May 2019, the Plaintiff had manufactured sufficient inventory to meet the entire market demand for L-Cysteine. [Id.].

Notwithstanding its approval of the Plaintiff's ELCYS product, the following month the FDA approved the Defendant's continued distribution of its product along with the previously approved Dear Healthcare Provider letter. [Doc. 31-2 at 50].

In late May 2019, the Defendant's executives reached out to the Plaintiff's executives to inquire whether the Plaintiff would be willing to license its "recently approved products," including ELCYS, to the Defendant. [Id. at ¶ 43]. The Plaintiff declined the Defendant's offer. [Id.].

After the FDA approved the Plaintiff's product, the Plaintiff made numerous efforts to get the Defendant to stop selling its unapproved product. Starting in May 2019, the Plaintiff repeatedly asked the FDA to remove L-Cysteine hydrochloride \*1010 injection from its drug shortage list and prohibit any further importation and distribution of the Defendant's unapproved product. [Doc. 1 at ¶ 49; Doc. 1-23]. Receiving no relief from the FDA, the Plaintiff sent letters to the CEO and Chairman of the Board of Defendant Sandoz's parent company, Novartis, A.G., on August 20, 2019. [Doc. 1-24]. Copying the FDA on the letter, the Plaintiff told Novartis about the allegedly improper and unethical conduct and asked that Novartis immediately stop importation and distribution of the L-Cysteine product. [Doc. 1 at ¶ 50; Doc. 1-24].

On September 3, 2019, the FDA declared an end to the L-Cysteine drug shortage. [Id. at ¶ 50; Doc. 1-25]. Around the same time, the FDA asked the Defendant to stop importing its L-Cysteine product. [Doc. 1-21]. The Defendant's stopped importing its L-Cysteine product in response to the FDA's request. [Doc. 1 at ¶ 45]. On September 25, 2019, the Plaintiff sent a letter to its customers stating that although "there is now an FDA approved L-Cysteine available in the US market[,]" the "FDA is allowing Sandoz to continue distributing its existing inventory ...." [Doc. 1-21 at 2].

\*\*4 On September 24, 2019, the Defendant responded to the Plaintiff's August 20 letter, acknowledging that the Plaintiff's ELCYS product had been approved by the FDA and that "the drug shortage has abated." [Doc. 1 at ¶ 51; Doc. 1-15]. The Defendant nevertheless confirmed that it had the FDA's permission to sell the product that it had already imported and expressed its intention to do so. [Id.]. The Plaintiff's marketing team claims to have observed customers buying or committing to buy up to a year's supply of the Defendant's product even after ELCYS received FDA approval. [Doc. 1 at ¶ 53].

On October 8, 2019, the FDA directed the Defendant to stop distribution distributing its L-Cysteine product. [Doc. 1-20]. The Defendant immediately complied with the FDA's request. [Doc. 1 at ¶ 45; Doc. 1-20]. Despite being the only FDA-approved L-Cysteine product on the market and having low aluminum levels, the Plaintiff's ELCYS has attained less than 20% of the L-Cysteine market while the Defendant "maintain[s] over" 80%. [Id. at ¶ 35, 58].

The Plaintiff's allegation in Paragraph 58 of the Complaint appears to facially contradict its allegation in Paragraph 45. If the Defendant discontinued sales of this product by October 8, 2019, then as of the date of the Plaintiff's filing (November 6, 2019), the Defendant no longer had *any* share of the market. [Doc. 1 at ¶¶ 45, 58]. Giving the Plaintiff the benefit of a very generous inference, this may mean that 80% of the *use* (rather than sales) of an L-Cysteine product in the United States as of November 6, 2019 was of the Defendant's product that had been sold prior to October 8, 2019.

#### III. STANDARD OF REVIEW

[3] To survive a motion to dismiss pursuant to Rule 12(b)(6), "a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.' "Ashcroft v. Iqbal, 556 U.S. 662, 678, 129 S.Ct. 1937, 173 L.Ed.2d 868 (2009) (quoting Bell Atlantic Corp. v. Twombly, 550 U.S. 544, 570, 127 S.Ct. 1955, 167 L.Ed.2d 929 (2007)). To be "plausible on its face," a plaintiff must demonstrate more than "a sheer possibility that a defendant has acted unlawfully." Iqbal, 556 U.S. at 678, 129 S.Ct. 1937.

[4] In reviewing the complaint, the Court must accept the truthfulness of all factual allegations but is not required to assume the truth of "bare legal conclusions." <u>Aziz v. Alcolac, Inc.</u>, 658 F.3d 388, 391 (4th Cir. 2011). "The mere recital of elements of a cause of action, supported only by conclusory

statements, is not sufficient to survive a motion made pursuant to \*1011 Rule 12(b)(6)." Walters v. McMahen, 684 F.3d 435, 439 (4th Cir. 2012).

[5] [6] [7] Determining whether a complaint states a plausible claim for relief is "a context-specific task," Francis v. Giacomelli, 588 F.3d 186, 193 (4th Cir. 2009), which requires the Court to assess whether the factual allegations of the complaint are sufficient "to raise the right to relief above the speculative level," Twombly, 550 U.S. at 555, 127 S.Ct. 1955. As the Fourth Circuit has explained:

To satisfy this standard, a plaintiff need not forecast evidence sufficient to prove the elements of the claim. However, the complaint must allege sufficient facts to establish those elements. Thus, while a plaintiff does not need to demonstrate in a complaint that the right to relief is probable, the complaint must advance the plaintiff's claim across the line from conceivable to plausible.

<u>Walters</u>, 684 F.3d at 439 (citations and internal quotation marks omitted).

#### IV. DISCUSSION

In its Motion to Dismiss the Complaint or, in the Alternative, Stay the Case Pending Referral to FDA, the Defendant argues that the Plaintiff's Chapter 75 and tortious interference with prospective business advantage claims are preempted by the Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 301 et seq., and that the Plaintiff's Lanham Act claim fails because it is inconsistent with the FDCA. [Doc. 29-1]. Specifically, the Defendant argues that the FDCA does not contain a private right of action to enforce its provisions and that the Plaintiff's state-law claims interfere with the federal regulatory regime because they are allegedly predicated on unenforced FDCA violations. [Id.]. The Defendant, therefore, argues that the Plaintiff's Complaint, as a matter of law, fails to state a claim upon which relief can be granted. The Plaintiff responds that the Complaint contains sufficient facts to support the Chapter 75, tortious interference with prospective business advantage, and Lanham Act claims and that those claims are not preempted by or inconsistent with the FDCA. [Doc. 38].

#### A. State Law Claims

\*\*5 [8] [9] [10] The Supremacy Clause of the Constitution makes evident that "state laws that conflict with federal law are 'without effect.' " Altria Grp., Inc. v. Good, 555 U.S. 70, 76, 129 S.Ct. 538, 172 L.Ed.2d 398 (2008) (citation omitted). There are three types of preemption under

the Supremacy Clause: (1) express preemption, (2) field preemption, and (3) conflict preemption. Id. at 76-77, 129 S.Ct. 538. Conflict preemption, the only type of preemption relevant here, exists where "there is an actual conflict between state and federal law," id., and the "state law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.' "Hillsborough Cnty., Fla. v. Automated Med. Labs., Inc., 471 U.S. 707, 713, 105 S.Ct. 2371, 85 L.Ed.2d 714 (1985) (citations and quotations omitted). For example, the Supreme Court has held that a state-law claim contrary to the FDCA is barred by conflict preemption because "the federal statutory scheme ... used by the [FDA] to achieve a somewhat delicate balance of statutory objectives" would be "skewed by allowing" a plaintiff to bring state-law claims. Buckman Co. v. Plaintiffs' Legal Comm., 531 U.S. 341, 348, 121 S.Ct. 1012, 148 L.Ed.2d 854 (2001). In evaluating whether federal law has preempted state law, the Court must look to "the purpose of Congress [as] the ultimate touchstone," while also "start[ing] with the assumption that the historic police powers of the States were not to be superseded ... unless \*1012 that was the clear and manifest purpose of Congress." Wyeth v. Levine, 555 U.S. 555, 565, 129 S.Ct. 1187, 173 L.Ed.2d 51 (2009).

The FDCA charges the FDA with "promot[ing] the public health by promptly and efficiently reviewing clinical research and taking appropriate action on the marketing of regulated products in a timely manner." 21 U.S.C. § 393(b)(1). In the FDCA, Congress required the FDA to "protect the public health" by making sure that "drugs are safe and effective." Id. § 393(b)(2)(B). The FDCA also empowers the FDA to combat drug shortages, See, e.g., id. at §§ 356c-1(a)(5), 356d, 356(e) (4).

[11] If a drug is marketed without prior FDA approval, the FDA may bring an enforcement action under the FDCA. See 21 U.S.C. §§ 332–34 (1982). The FDCA gives the FDA "complete discretion" to "decide how and when [it] should be exercised." Heckler v. Chaney, 470 U.S. at 835, 105 S.Ct. 1649. The FDCA provides that "all such proceedings for the enforcement, or to restrain violations, of [the FDCA] shall be by and in the name of the United States." As such, "[t]he FDCA leaves no doubt that it is the Federal Government rather than private litigants who are authorized to file suit for noncompliance ...." Buckman, 531 U.S. at 349 n. 4, 121 S.Ct. 1012.

[12] [13] The FDCA's prohibition on private actions, however, would be "thwarted if savvy plaintiffs can label

as arising under a state law for which there exists a private enforcement mechanism a claim that in substance seeks to enforce the FDCA." Loreto v. Procter & Gamble Co., 515 F. App'x 576, 579 (6th Cir. 2013). As such, "private litigants may not bring a state-law claim against a defendant when the state-law claim is in substance (even if not in form) a claim for violating the FDCA." Id. (citations and internal quotation marks omitted); see also American Home Products Corp. v. Johnson & Johnson, 436 F. Supp. 785, 797 (S.D.N.Y. 1977) (noting that "state unfair competition laws [are] not the proper legal vehicle in which to vindicate the public's interest in health and safety."). Likewise, "[t]here can be no state law cause of action if a plaintiff's true goal is to privately enforce alleged violations of the FDCA." Borchenko v. L'Oreal USA, Inc., 389 F.Supp.3d 769, 773 (C.D. Cal. 2019) (citation and quotations omitted).

[16] "The test for determining whether a state [14][15] law claim is impliedly preempted is whether or not the claim would exist in the absence of the FDCA." Evans v. Rich, No. 5:13-CV-868-BO, 2014 WL 2535221, at \*2 (E.D.N.C. June 5, 2014) (citing Loreto, 515 Fed. App'x at 579). " 'As the Sixth Circuit has explained, any claim that relies on the FDCA or its implementing regulations '[a]s a critical element' is barred by § 337(a).' "Agee v. Alphatec Spine, Inc., No. 1:15-CV-750, 2017 WL 5706002, at \*3 (S.D. Ohio Mar. 27, 2017) (quoting Marsh v. Genentech, Inc., 693 F.3d 546, 553 (6th Cir. 2012)); see also In re Darvocet, Darvon, & Propoxyphene Prods. Liab. Litig., 756 F.3d 917, 936 (6th Cir. 2014) ("claims" premised on "a violation of the FDCA" are impliedly preempted "because the FDA has the exclusive power to enforce the FDCA" and there is "no private right to enforce the statute"). For example, "a state-law claim that the defendant made misrepresentations to the FDA is preempted because such a claim would not exist absent the federal regulatory scheme established by the FDCA." Riley v. Cordis Corp., 625 F. Supp. 2d 769, 777 (D. Minn. 2009) (citing Buckman, 531 U.S. at 352-53, 121 S.Ct. 1012). Similarly, courts have found implied preemption applies to claims like "breach of warranty, negligence per se, design defect, and failure \*1013 to warn." Evans, 2014 WL 2535221, at \*2 (citing in re Medtronic, Inc. Sprint Fidelis Leads Products Liab. Litig., 592 F.Supp.2d 1147, 1159-64 (D. Minn. 2009)).

\*\*6 With this preemption framework in mind, the Court now turns to each of the Plaintiff's state law claims.

#### 1. Chapter 75 Claim

or deceptive act or practice; (2) in or affecting commerce; which (3) proximately caused actual injury to the claimant or its business. N.C. Gen. Stat. § 75-1.1. An act is deceptive "if it has a tendency or capacity to deceive." Rahamankhan Tobacco Enterprises Pvt. Ltd. v. Evans MacTavish Agricraft, Inc., 989 F.Supp.2d 471, 477 (E.D.N.C. 2013). An act is unfair "if it offends established public policy," "is immoral, unethical, oppressive, unscrupulous, or substantially injurious to consumers," or "amounts to an inequitable assertion of ... power or position." Id. A deceptive practice is one that has "the capacity or tendency to deceive the average consumer, but proof of actual deception is not required." Spartan Leasing, Inc. v. Pollard, 101 N.C. App. 450, 461, 400 S.E.2d 476, 482 (1991). "What is an unfair or deceptive trade practice usually depends upon the facts of each case and the impact the practice has in the marketplace." Durling v. King, 146 N.C. App. 483, 489, 554 S.E.2d 1, 4 (2001) (citing Pan American World Airways, Inc. v. United States, 371 U.S. 296, 83 S.Ct. 476, 9 L.Ed.2d 325 (1963)).

The Plaintiff generally claims that the Defendant violated Chapter 75 through its "unfair and deceptive actions to import, sell, and stuff the distribution channels with its unapproved product." [Doc. 1 at ¶ 1]. Specifically, the Plaintiff alleges that the Defendant acted unlawfully by (1) importing and selling an illegal product, [id. at ¶¶ 6, 8, 36, 37, 66, 67, 69, 77, 79]; (2) seeking a "Memorandum of Discretion," and numerous extensions of that Memorandum, to import an illegal product, [id. at ¶¶ 40, 69]; (3) failing to update its 2018 Dear Healthcare Provider letter after the FDA approved ELCYS, [id. at ¶ 69]; (4) failing to warn its customers about its product's aluminum content, [id.]; and (5) misusing "its incumbent status in the market and its huge market power and reach to block hospitals and distributors from switching" to the Plaintiff's L-Cysteine product. [Id.].

#### a. Importing and Selling an Illegal Product

The Plaintiff claims that the Defendant violated Chapter 75 by importing and selling its L-Cysteine product because such conduct is the type of "'immoral, unethical, [and] unscrupulous behavior'" that Chapter 75 "deems as 'unfair.' " [Doc. 1 at ¶ 68 (quoting State ex rel. Cooper v. NCCS Loans, Inc., 174 N.C. App. 630, 640 (2005))]. The crux of the

Plaintiff's Chapter 75 claim is that the Defendant's L-Cysteine product was unlawful, dangerous, and unfit for importation or sale, and that the FDA acted unlawfully by letting the [18] [19] A Chapter 75 claim requires (1) an unfair Defendant import and sell that product. 8 Stated differently, the Plaintiff's state-law claim challenges the FDA's decision not to bring enforcement proceedings against the Defendant under the FDCA for importing and selling an unapproved and unsafe drug.

- The Plaintiff concedes that the Defendant's "misconduct originated in a violation of the FDCA-the import and sale of the unapproved product." [Doc. 1-38 at 7].
- [21] The Plaintiff's Chapter 75 claim related to the Defendant's sale and importation of the L-Cysteine product is preempted. The FDCA contains no private right of action and gives the FDA "complete \*1014 discretion" to decide whether to bring enforcement proceedings. Heckler, 470 U.S. at 835, 105 S.Ct. 1649. As such, the "FDA has power to determine whether particular drugs require an approved NDA [New Drug Application] in order to be sold to the public." Weinberger v. Hynson, Westcott & Dunning, Inc., 412 U.S. 609, 624, 93 S.Ct. 2469, 37 L.Ed.2d 207 (1973). The Plaintiff does "not have the authority to stand in the shoes of the FDA to determine whether [the defendant's] sale of the products at issue amounts to the sale of an unapproved drug under the FDCA. This enforcement authority [lies] exclusively with the FDA." Allergan, Inc. v. Athena Cosmetics, Inc., 738 F.3d 1350, 1359 (Fed. Cir. 2013); see also Agee, 2017 WL 5706002, at \*5 (stating that if "the distribution of [the product] was in violation of the FDCA and relevant FDA regulations ... it is the sole responsibility and privilege of the federal government, and not private plaintiffs, to bring a suit to enforce those violations."). The crux of the Plaintiff's Chapter 75 claim is a challenge to whether the importation and sale of the Defendant's L-Cysteine product are lawful under the FDCA. As such, the Plaintiff is preempted from making that claim.

The Plaintiff's claim related to the Defendant's importation and sale of its L-Cysteine product is also preempted because it would stand "as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." Hillsborough Cnty., 471 U.S. at 713, 105 S.Ct. 2371 (citations omitted). The FDCA empowers the FDA to combat drug shortages, see, e.g., 21 U.S.C. §§ 356c-1(a)(5), 356d, 356(e) (4), while also ensuring "that any product regulated by the FDA is 'safe' and 'effective' for its intended use." FDA v. Brown & Williamson Tobacco Corp., 529 U.S. 120, 133, 120 S.Ct. 1291, 146 L.Ed.2d 121 (2000) (citing 21 U.S.C. § 393(b)

(2)). As such, the FDA "must evaluate the risks associated" with a drug shortage when deciding to bring an enforcement action under the FDCA. 21 U.S.C. § 356d(c). Allowing a state-law claim challenging the FDA's discretionary refusal to bring an enforcement action under the FDCA against the Defendant would therefore thwart the FDA's purpose. Hillsborough Cnty., 471 U.S. at 713, 105 S.Ct. 2371 (citations omitted). Other courts have rejected similar claims. See Loreto, 515 F. App'x at 579 (stating that "[a] plaintiff cannot use a state-claim to argue that a defendant's product was " 'illegal,' and had [consumers] known it, they wouldn't have purchased the products" because that "theory of liability depends entirely upon an FDCA violation.").

Allowing a Chapter 75 claim based on the safety of the Defendant's L-Cysteine product would also skew "the federal statutory scheme ... used by the [FDA] to achieve a somewhat delicate balance of statutory objectives." Buckman, 531 U.S. at 348, 121 S.Ct. 1012. Here, the record shows that the FDA engaged in a prolonged effort to balance those objectives, as well as the various interests, before deciding to let the Defendant to distribute its L-Cysteine product. That decision necessarily involved balancing the risks inherent in a drug shortage with the safety risks of allowing the importation and sale of an unapproved product. After ELCYS received FDA approval, the FDA still had to account for the risk that ELCYS might not be able to meet the entire market demand for L-Cysteine, the risk of supply chain issues during the transition from the Defendant's L-Cysteine product to ELCYS, and other associated risks. Allowing \*1015 state-law claims would disrupt the delicate and considered balance that the FDA struck. In short, the FDA was charged with addressing a shortage of a critical medical product. The FDA made its determination of the best solution of the problem. For the Plaintiff to now second guess the FDA's decision in a civil action based on state law would render the FDA's authority to be a nullity.

The FDA also had to balance the competing interests of these parties, each of whom sought and advocated for different outcomes. While the Plaintiff wanted the FDA to remove the Defendant's L-Cysteine product from the market almost immediately after ELCYS received FDA approval, the Defendant wanted a chance to sell the inventory *it* created in response to the FDA's requests to help with the drug shortage.

\*\*8 The Plaintiff's claim related to the Defendant's importation and sale of its L-Cysteine product presents a similar issue to the one addressed in Drager v. PLIVA USA,

Inc., 741 F.3d 470, 479 (4th Cir. 2014). In <u>Drager</u>, a consumer injured by a drug brought state-law claims alleging that the manufacturer's label that was approved by the FDA was inadequate. The Fourth Circuit held that the state-law claims were preempted by federal law because they would force the manufacturer to either "leave the market or accept tort liability" despite the manufacturer's compliance with the FDA's edicts. <u>Id.</u> The Fourth Circuit explained that the Hobson's choice presented in such a situation illustrates how allowing a state-law claim can subvert the federal regulatory scheme, thus requiring the preemption of such state claims. Id.

The logic of <u>Drager</u> is applicable to this case. Here, the FDA issued a Memorandum of Discretion, and several renewals of that Memorandum, allowing the Defendant temporary permission to import and sell its L-Cysteine product. [Doc. 1 at ¶¶ 40, 44]. Notwithstanding the Defendant's permission from the FDA, a viable Chapter 75 claim related to the import and sale of the L-Cysteine product would have nonetheless forced the Defendant "to leave the market or accept tort liability." <u>Id.</u> This is precisely the type of claim that the Fourth Circuit held in <u>Drager</u> must be preempted.

This case, just like <u>Drager</u>, is unlike the failure-to-warn cases that the Plaintiff cites. [See Doc. 38 at 11]. For example, in Wyeth v. Levine, the Supreme Court explained that a state-law claim was not preempted by the FDCA's labeling requirements because those "requirements create a floor, not a ceiling, for state regulation." 555 U.S. 555, 563, 129 S.Ct. 1187, 173 L.Ed.2d 51 (2009). As such, the Court in Wyeth found that the state-law claim did not "stand as an obstacle to the accomplishment of Congress' purposes in the FDCA" because the defendant could have remained in the market by adding additional warnings that would comply with both the state-law and federal-law requirements. Id. at 581, 129 S.Ct. 1187. That is not the case here, where the Plaintiff asserts that the only way to comply with state law would have been for the Defendant to leave the market, notwithstanding the Defendant's compliance with the FDA's directives. Drager, 741 F.3d at 479. Likewise, Wyeth was a claim by an injured patient against a drug company related to a purportedly deficient label, not a claim by a competitor seeking to prevent the distribution of a purportedly unsafe drug. That distinction is important because removing a product that the FDA expressly allowed in the market to address a drug shortage interferes with federal objectives in a way that changing a product's label does not. See Zogenix, Inc. v. Patrick, No. CIV.A. 14-11689-RWZ, 2014 WL 1454696, at \*2 (D. Mass.

Apr. 15, 2014) (stating that "<u>Wyeth</u> is a drug labeling case, and defendant present no evidence of persuasive argument that its reasoning should control" when determining whether a state \*1016 law can contravene the FDA's decision to allow the sale of a drug.).

The Plaintiff also relies on Allergan, [Doc. 38 at 12], where the Federal Circuit found that a state-law claim based on the marketing, sale, and distribution or an unapproved drug was not preempted by the FDCA. Id. In that decision, however, the Federal Circuit focused on the fact that the state-law requirements paralleled the FDCA requirements, in a situation where the FDA had *not* given the defendant explicit permission to market, sell, or distribute the drug at issue. Allergan, 738 F.3d at 1355. That case has no application here, because the FDA gave explicit permission to the Defendant to distribute its product. The Plaintiff's state-law claim would entirely undercut the FDA's decision and authority.

\*\*9 Instead, Zogenix, Inc. v. Patrick, No. CIV.A. 14-11689-RWZ, 2014 WL 1454696, at \*2 (D. Mass. Apr. 15, 2014) is more instructive. In that case, Massachusetts' ban on the sale of an FDA-approved drug was preempted because allowing the state to "countermand the FDA's determinations and substitute its own requirements [would] undermine the FDA's ability to make drugs available to promote and protect the public health." Id. As such, the state-tort claim would interfere with " 'the accomplishment and execution of' an important federal objective." Id. (quoting Hines v. Davidowitz, 312 U.S. 52, 67, 61 S.Ct. 399, 85 L.Ed. 581 (1941)). Like the plaintiff in Zogenix, the Plaintiff herein seeks to overturn the FDA's decision to allow the importation and sale of a product. While the Plaintiff argues that Zogenix is distinguishable because that case involved an FDA-approved drug, rather than drug allowed to be imported and sold under a Memorandum of Discretion, [Doc. 38 at 12], that distinction matters little for preemption purposes. The outcome of the FDA's decision in both instances, whether made through its approval process or through an exercise of discretion to address a shortage, was to allow the drug to be imported and sold. The Plaintiff cannot use a state-law claim to contravene the FDA's decision and remove that drug from the market because that would interfere with the federal objective of allowing that drug to remain available. See id. at \*2-3. This is particularly true in a case such as this one where the FDA was trying to address a crucial shortage.

The Plaintiff next argues that the FDA's Memorandum of Discretion allowing the Defendant to import and sell its L-

Cysteine product was illegitimate because the FDA's entire shortage program was declared illegal by the D.C. Circuit in Cook v. FDA, 733 F.3d 1 (D.C. Cir. 2013). [Doc. 1 at ¶ 39]. The claim in <u>Cook</u> was brought under the Administrative Procedures Act against the FDA regarding the importation of sodium thiopental from unregistered foreign laboratories for use in lethal injections. 733 F.3d at 10. Cook held that the FDA is required to examine samples of imported drugs manufactured in unregistered facilities to determine if those drugs violate FDCA requirements. Id. at 9 ("We do not say the FDA must sample and examine every article under its jurisdiction that is offered for import but only that it must sample and examine drugs manufactured ... in an unregistered establishment."). 10 Cook specifically allowed the FDA to "exercise enforcement discretion to allow the domestic distribution of a misbranded or unapproved new drug" and "invoke its express statutory authority to permit the importation of an unapproved new drug." Id. at 10. Contrary to the \*1017 Plaintiff's argument, Cook did not go as far as to hold that the FDA's shortage program is illegal. Id. at 10.

While <u>Cook</u> involved importation from an unregistered facility, this case involves importation from a registered facility. [Doc. 1-22 at 5]; <u>Cook</u>, 733 F.3d at 9.

<u>Cook</u> is simply inapposite here. Unlike <u>Cook</u>, the Plaintiff did not bring this action against the FDA seeking judicial review of agency action (or inaction) under the Administrative Procedures Act. The FDA is not even a party to this case. Instead, this case presents a dispute between two drug manufacturers. Moreover, the Plaintiff cites no authority for the proposition that the FDA's refusal to bring enforcement proceedings would even be reviewable under the circumstances found here as it was in <u>Cook</u>. <u>See Heckler</u> v. Chaney, 470 U.S. 821, 832-33, 105 S.Ct. 1649, 84 L.Ed.2d 714 (1985) (stating that "an agency's decision not to take enforcement action should be presumed immune from judicial review" unless the "substantive statute has provided guidelines for the agency to follow in exercising its enforcement powers."). While the presumption against judicial review did not apply in Cook because the FDCA "provided guidelines for the agency to follow in exercising its enforcement powers" concerning unregistered foreign facilities, Cook, 733 F.3d at 6, the Plaintiff identifies no such guidelines that apply to the registered facility at issue here. As such, the FDA's enforcement decisions concerning registered laboratories appear to be immune from judicial review because the FDCA's enforcement provisions commit "complete discretion to the FDA to decide how and when

they should be exercised." <u>Heckler</u>, 470 U.S. at 835, 105 S.Ct. 1649.

\*\*10 For all these reasons, the Plaintiff's Chapter 75 claim based on the Defendant's sale or importation of its L-Cysteine product must be dismissed as preempted.

#### b. Seeking a Memorandum of Discretion

The Plaintiff next claims that the Defendant violated Chapter 75 by seeking a renewal of the Memorandum of Discretion in June 2019 after ELCYS received FDA approval to continue selling its L-Cysteine product. [Doc. 1 at ¶¶ 40, 69]. In this sense, however, the Plaintiff's true quarrel is with the FDA granting the Defendant's June 2019 request for a renewal of the Memorandum of Discretion, not with the Defendant's seeking the renewal. The FDA did not declare the end of the drug shortage until September 3, 2019. [Id. at ¶ 50; Doc. 1-25]. It was not unfair or deceptive for the Defendant to ask if it could continue importing and selling its L-Cysteine product while the drug shortage continued. That is particularly true considering that it was this drug shortage that originally led the FDA to ask the Defendant to import and sell its L-Cysteine product. [Doc. 1-15].

Moreover, the Plaintiff has failed to plausibly allege that the Defendant's requests for the Memorandum of Discretion or the subsequent renewals of that Memorandum involved any unfairness or deception. The FDA was fully aware of the development of ELCYS, its approval status and production status, the differences in the aluminum content between the ELCYS and the Defendant's L-Cysteine product, as well as the state of the L-Cysteine market when it renewed the Memorandum of Discretion in June 2019. Despite that knowledge, the FDA rebuffed the Plaintiff's requests to end the drug shortage until September 3, 2019, waited until that time to halt importation of the Defendant's L-Cysteine product, and waited until October 8, 2019 to halt sales of that product. [Docs. 1-23, 1-20, 1-21].

Though the FDA is not a party to this case, it has issued guidance explaining that it generally weans unapproved products off the market once a competing product has been approved. See FDA, Marketed \*1018 Unapproved Drugs — Compliance Policy Guide: Sec. 440.100, Marketed New Drugs without Approved NDAs or ANDAs (Sep. 2011) at 7-8 ("When a company obtains approval to market a product that other companies are marketing without approval,

FDA normally intends to allow a grace period of roughly 1 year from the date of approval of the product before it will initiate enforcement action (*e.g.*, seizure or injunction) against marketed unapproved products of the same type." "To assist in an orderly transition to the approved product(s), in implementing a grace period, FDA may identify interim dates by which firms should first cease manufacturing unapproved forms of the drug product, and later cease distributing the unapproved product."). That guidance explains the FDA's actions here. In fact, rather than allowing the Defendant a one-year grace period per its regulations, it gave the Defendant only six months (April to October 2019) to continue importing and selling its L-Cysteine product before halting importation of the product and then halting sales of the product. <sup>11</sup>

Notably, the Plaintiff did not have sufficient production to satisfy the market for a significant portion of that six-month period. The Plaintiff makes no allegations regarding the adequacy of its distribution network to distribute what it was able to manufacture during that time

\*\*11 The Plaintiff does not allege that the FDA's guidance-based decisions were a result of any false or misleading actions on the part of the Defendant. The Plaintiff only alleges that the Defendant committed an unfair or deceptive act by merely seeking renewal. That is insufficient to support a Chapter 75 claim. For these reasons, the Plaintiff's Chapter 75 claim based on the Defendant seeking a renewed Memorandum of Discretion in June 2019 is without merit, and that claim must be dismissed.

#### c. Failing to Update Dear Healthcare Provider Letter

[22] The Plaintiff next claims that the Defendant violated Chapter 75 by failing to update the Dear Healthcare Provider letter that accompanied its L-Cysteine product to inform customers that ELCYS had received FDA approval. [Doc. 1 at ¶¶ 9, 41, 69]. Specifically, the Plaintiff alleges that the Defendant sent out Dear Healthcare Provider letters in March 2016, [Doc. 1-17], and September 2018 [Doc. 1-18], stating that "there are currently no FDA-approved L-Cysteine Injection products in the United States" and failed to send a new letter to update that statement until six months after ELCYS received FDA approval. [Doc. 1 at ¶ 9, 41, 46, 69; Doc. 1-21]. <sup>12</sup>

12

The Plaintiff's Complaint fails to identify the particular communication that provides a basis for the alleged Chapter 75 violation. The Plaintiff alleges, on information and belief, that the Defendant sent Dear Healthcare Provider letters with incorrect information regarding ELCYS' FDA approval status after it had received FDA approval on April 16, 2019. [Doc. 1 at ¶¶ 9, 46]. The Plaintiff's Complaint, however, only attaches Dear Healthcare Provider letters sent on March 1, 2016, and September 1, 2018. [Doc. 1-17; 1-18]. The Plaintiff provides no communication from after April 16, 2019, where the Defendant falsely states that its L-Cysteine product is the only L-Cysteine product available in the United States. The only communication that the Plaintiff provides from that period is from September 25, 2019, when the Defendant informed customers that "there is now an FDA approved L-Cysteine available in the US market." [Doc. 1-21].

The Defendant argues that the Plaintiff's claim is preempted because the Dear Healthcare Provider letters were mandated, overseen, and preapproved by the FDA as part of its decision to grant a Memorandum of Discretion to the Defendant under the FDCA. [Doc. 29-1 at 17]. The Defendant also argues that it did not violate \*1019 Chapter 75 because it sent a new letter to tell customers that "there is now an FDA approved L-Cysteine available in the U.S. market" roughly five months after ELCYS received FDA approval. [Doc. 29-1 at 18 (citing Doc. 1 at ¶¶ 46)].

"Manufacturers and distributors of drugs and the Food and Drug Administration occasionally are required to mail important information about drugs to physicians and others responsible for patient care" in so-called Dear Healthcare Provider letters. See 21 C.F.R. § 200.5. The FDA can mandate and oversee the distribution of Dear Healthcare Provider letters in conjunction with its oversight of drug shortages. [Doc. 29-1 at 17]; Center for Drug Evaluation and Research, Drug Shortage Management, Manual of Policies and Procedures 4190.1 at 10 ("When a potential or actual shortage might be resolved by obtaining a drug from an alternate source," the FDA will "[c]oordinate issuance and clearance of a Dear Healthcare Provider Letter ...."). While no explicit statutory or regulatory provisions set forth the circumstances under which a drug manufacturer must issue a Dear Healthcare Provider letter, the FDA has brought enforcement actions under the FDCA where Dear Healthcare Provider letters contained "false or misleading" statements. State ex rel. McGraw v. Johnson & Johnson, 226 W. Va. 677, 682, 704 S.E.2d 677, 682 (2010).

\*\*12 Here, the Memorandum of Discretion and the subsequent renewals of that Memorandum show that the Defendant distributed the Dear Healthcare Provider letters at the FDA's direction and with the FDA's approval. [Doc. 31-2 at 41-59]. The distribution of those letters was one of the FDA's conditions for not exercising its enforcement authority against the Defendant's L-Cysteine product. [Id.]. Under those conditions, the FDA explicitly approved the language contained in the Defendant's Dear Healthcare Provider letters and any revisions of those letters required FDA approval. [Doc. 31-2 at 41, 43, 46-50].

Notably, the last Memorandum of Discretion renewal occurred on June 21, 2019, after the FDA approved ELCYS, after the Plaintiff had produced sufficient ELCYS for the entire market, and after the Plaintiff had started shipping ELCYS. [Id. at 50; Doc. 1 at ¶ 33, 34]. The FDA, however, did not require the Defendant to update its Dear Healthcare Provider letter after ELCYS was approved. Instead, the June 21, 2019 renewal mandated (under threat of enforcement action) that "[t]he previously reviewed Dear Healthcare Provider letter continues to accompany" the Defendant's product. [Doc. 31-2 at 50 (emphasis added)]. That previously reviewed letter stated that "there are currently no FDA-approved L-Cysteine Injection products in the United States." [Doc. 1-18]. Accordingly, the FDA not only approved the statement in the Dear Healthcare Provider letter about which the Plaintiff complains, but required the Defendant to make that statement.

Nevertheless, the Plaintiff argues that the Defendant should face state tort liability for failing to ask the FDA for permission to update the Dear Healthcare Provider letter after the FDA approved ELCYS. [Id. at ¶ 69]. The Memorandum of Discretion and its subsequent renewals prohibited the Defendant from unilaterally changing the statements contained in the letter, including the statement about which the Plaintiff complains. [Doc. 31-2 at 50; see also Doc. 31-2 at 43 (stating that "if Sandoz makes further edits to this letter, [the FDA] requests the opportunity to review before the letter is printed and distributed")]. The Supreme Court has held that "when a party cannot satisfy its state duties without the Federal \*1020 Government's special permission and assistance, which is dependent on the exercise of judgment by a federal agency, that party cannot independently satisfy those state duties for pre-emption purposes." PLIVA, Inc. v. Mensing, 564 U.S. 604, 623-24, 131 S.Ct. 2567, 180 L.Ed.2d 580 (2011). That is because "[t]he only action the [Defendant] could independently take—asking for the FDA's help—is not

a matter of state-law concern." <u>Id.</u> at 624, 131 S.Ct. 2567. To the extent that the Plaintiff's Chapter 75 claim is based on the Defendant's failure to update its Dear Healthcare Provider letter, that claim is preempted because the FDA controlled the contents of the Dear Healthcare Provider letters and the Defendant could not unilaterally update those letters without the FDA's involvement and approval, which is not a matter of state-law concern. Therefore, the failure to change the contents of the letter cannot be a basis for a state law claim.

While the Plaintiff asserts that the Defendant "failed to inform its customers of the FDA-approved status of Exela's product at least until September 25, 2019[,]" [Doc. 1 at ¶ 69], that allegation also cannot support a Chapter 75 claim. As discussed above, the FDA's scheme for controlling the risks associated with the Defendant's product required the Defendant to communicate with customers through Dear Healthcare Provider letters. That arrangement and process would have been undermined if the Defendant sent other communications to customers contradicting the contents of the FDA-approved Dear Healthcare Provider letters. The Defendant's failure to subvert the FDA's scheme and risk enforcement action by sending a communication other than a Dear Healthcare Provider letter cannot give rise to a Chapter 75 claim.

#### d. Failing to Warn Customers About Aluminum Content

\*\*13 [23] The Plaintiff next claims that the Defendant violated Chapter 75 by failing to warn its customers that its L-Cysteine product had a higher aluminum content than the standard that the FDA required ELCYS to meet and by failing to tell its customers about the difference in aluminum content between the two products. [Doc. 1 at  $\P$  69]. The Plaintiff also alleges that the Defendant did not update its Dear Healthcare Provider letters or "distribute any other formal communication to the field to inform its customers that the aluminum levels of its unapproved product far exceed" the standard that the FDA required ELCYS to meet to receive approval. [Id. at  $\P$  9]. <sup>13</sup>

Regarding the Plaintiff's allegations concerning the Dear Healthcare Provider letter, <u>see</u> Part IV.A.1.c, <u>supra</u>.

To begin, what the Plaintiff refers to as "FDA standards" are not standards at all. The relevant regulations do not set any upper limit on aluminum content for small volume parenteral drug products like the Defendant's L-Cysteine

product. See 21 C.F.R. § 201.323. Moreover, the letter where the Plaintiff contends that the FDA provided its aluminum content standard "does not constitute an official agency determination." Schering-Plough Healthcare Prod., Inc. v. Schwarz Pharma, Inc., 547 F. Supp. 2d 939, 947 (E.D. Wis. 2008), amended, No. 07-CV-642, 2009 WL 151573 (E.D. Wis. Jan. 22, 2009) (collecting cases); see also Dietary Supplemental Coal., Inc. v. Sullivan, 978 F.2d 560, 563 (9th Cir. 1992) (stating that "regulatory letters do not constitute final agency action."). Indeed, the FDA later explained to the Plaintiff that the Defendant's L-Cysteine product had aluminum levels that were "well within \*1021 the standards agreed upon with FDA" and that "[i]t is thus inappropriate to suggest that the Sandoz product is somehow unsafe." [Doc. 1-15]. As such, the fact that the FDA required the Plaintiff's ELCYS product to meet a certain aluminum level to receive FDA approval did not create a binding limitation on other drugs, especially ones that do not seek FDA approval like the Defendant's. In this argument, the Plaintiff conflates the level that needed to be met to receive temporary permission with the level for permanent approval.

The Plaintiff further argues that the Defendant violated Chapter 75 by failing to tell its customers about the difference in aluminum content between the Defendant and the Plaintiff's products. [Doc. 1 at ¶ 69]. The Plaintiff has cited no authority for the proposition that a merchant's failure to inform its customers as to how its product compares unfavorably to a competitor's product constitutes a deceptive trade practice. There is no basis to conclude that the law imposes such obligation.

The Plaintiff's dispute appears to be with the FDA for temporarily permitting importation and sale of a drug that did not meet the same aluminum levels that the FDA required ELCYS to meet for permanent approval. The Plaintiff cannot, however, use a state-law claim against a competitor to "countermand the FDA's determinations and substitute its own requirements" regarding the permissible aluminum content of the Defendant's L-Cysteine product. Zogenix, 2014 WL 1454696, at \*2. If the Plaintiff were allowed to bring such a claim, it would stand "in the way of 'the accomplishment and execution of' an important federal objective" by undermining "the FDA's ability to make drugs available to promote and protect the public health." Id. (quoting Hines v. Davidowitz, 312 U.S. 52, 67, 61 S.Ct. 399, 85 L.Ed. 581 (1941)). "The Constitution does not allow it to do so." Id.

As such, to the extent that the Plaintiff's Chapter 75 claim is based on the Defendant failing to meet the same aluminum content level that ELCYS was required to meet or on the Defendant failing to affirmatively advertise the differences between the two products, that claim must be dismissed as preempted and as failing to state a claim upon which relief can be granted.

#### e. Oversupplying Customers

\*\*14 The Plaintiff next argues that the Defendant violated Chapter 75 by "oversupplying customers and flooding distribution channels with its unapproved product to prevent them from purchasing [ELCYS]." [Doc. 1 at ¶ 69]. In short, the Plaintiff bases this claim on the fact that the Defendant imported, marketed, and sold a product that it was permitted by the FDA to import, market, and sell, and in quantities that did not exceed that permission.

As discussed previously, the Plaintiff is preempted from bringing a state-law claim to challenge the FDA's decision to allow the Plaintiff to import and sell its L-Cysteine product because there is no private right of action in the FDCA and the FDA is the sole entity that can bring enforcement actions to halt the sale and importation of drugs. In re Darvocet, Darvon, & Propoxyphene Prods. Liab. Litig., 756 F.3d 917, 936 (6th Cir. 2014) As such, the Plaintiff is preempted from bringing a Chapter 75 claim against the Defendant based on the volume of its L-Cysteine product sales.

#### f. Misusing Incumbent Status

Finally, the Plaintiff argues that the Defendant violated Chapter 75 by misusing "its incumbent status in the market and its huge market power and reach to block hospitals and distributors from switching" \*1022 to ELCYS. [Id. at ¶ 70]. It bears repeating that the Plaintiff's claims cannot be based merely on the Defendant's importation or sale of its L-Cysteine product because those claims are preempted.

The Defendant's sales were permitted by the FDA and the Plaintiff does not identify any act, other than the sales themselves, that constituted an unfair or deceptive act or an inequitable assertion of power. The volume of the sales, and the timing of those sales, as permitted by the FDA, are not suitable bases for a Chapter 75 claim. Moreover, an incumbent market competitor's sale of its inventory does

not become an unfair or deceptive act simply because those sales come at the expense of a smaller market competitor. The Plaintiff has cited no authority for this proposition. As such, the Plaintiff cannot base its Chapter 75 claim on the Defendant's incumbent status in the market or its volume of sales before exiting the market.

For all these reasons, the Plaintiff's Chapter 75 claim is dismissed.

### 2. Interference with Prospective Economic Advantage Claim

[24] The Plaintiff next claims that the Defendant illegally interfered with its prospective economic advantage by continuing to sell its unapproved L-Cysteine product after ELCYS received approval from the FDA. [Doc. 1 at ¶¶ 75-81].

[27] Tortious interference with prospective [25] [26] economic advantage "arises when a party interferes with a business relationship 'by maliciously inducing a person not to enter into a contract with a third person, which he would have entered into but for the interference, ... if damage proximately ensues, when this interference is done not in the legitimate exercise of the interfering person's rights." Beverage Sys. of the Carolinas, LLC v. Associated Beverage Repair, LLC, 368 N.C. 693, 701, 784 S.E.2d 457, 463 (2016) (quoting Spartan Equip. Co. v. Air Placement Equip. Co., 263 N.C. 549, 559, 140 S.E.2d 3, 11 (1965)). Because the interference must be done outside of the legitimate exercise of the interfering person's rights, "[i]nterference with a contract is justified if it is motivated by a legitimate business purpose, as when the plaintiff and the defendant ... are competitors." Id., 368 N.C. at 700, 784 S.E.2d at 463 (citations and quotations omitted). To survive dismissal, a complaint alleging tortious interference "must admit of no motive for interference other than malice." Pinewood Homes, Inc. v. Harris, 184 N.C. App. 597, 605, 646 S.E.2d 826, 832-33 (2007).

\*\*15 The Plaintiff tries to meet this element of the tort of intererence by alleging that the Defendant's "actions were not an exercise of any legitimate right of its own" because "it is illegal to introduce" an unapproved drug into interstate commerce. [Doc. 1 at ¶ 79 (citing 21 U.S.C. §§ 331(d), 355(a); Cook, 733 F.3d at 9-10)]. Again, the cornerstone of the Plaintiff's claim is this assertion that it is somehow "illegal" for the Defendant to do precisely what the FDA

gave the Defendant permission to do. As such, this claim again attempts to enforce the FDCA against the Defendant for importing and selling an illegal drug. The FDA, however, is the only entity that can bring a claim against the Defendant for its alleged introduction of an illegal drug into interstate commerce. See Allergan, Inc. v. Athena Cosmetics, Inc., 738 F.3d 1350, 1359 (Fed. Cir. 2013). The Plaintiff is preempted from bringing a claim based on the Defendant having no legal right to make the sales.

[28] The Plaintiff's allegations also show that the Defendant was merely a competitor motivated by a legitimate business purpose when it imported and sold its \*1023 L-Cysteine product. Beverage Sys. of the Carolinas, 368 N.C. at 701, 784 S.E.2d at 463. The Plaintiff's own allegations show that the crux of the Defendant's alleged wrongdoing is that it "schemed to stay, compete, and dominate the L-Cysteine market for months" and thereby prevent "the vast majority of customers from buying [the Plaintiff's] FDAapproved product." [Doc. 41 at ¶ 78] (emphasis added). Those allegations, however, simply show a market competitor motivated by a legitimate business purpose—selling its existing inventory. The Plaintiff has failed to plausibly allege that the Defendant, as its competitor, had no legitimate business purpose for selling its inventory after ELCYS had been approved. As such, the Plaintiff's allegations concerning interference with prospective economic advantage fail to state a claim upon which relief can be granted and must be dismissed.

#### B. Lanham Act Claim

The Plaintiff next claims that the Defendant violated the Lanham Act by making "false and misleading representations in the course of selling its unapproved L-Cysteine product." [Doc. 1 at ¶ 84]. According to the Plaintiff, those false and misleading representations

include, but are not limited to failing to update its Dear Healthcare Provider letter to inform customers of the FDA approved status and availability of [the Plaintiff's] product; providing a link on its product website to a database that says nothing about the aluminum content of [the Defendant's] product while clearly indicating the low aluminum content of FDA-approved ELCYS; failing to inform customers that the aluminum levels of [the Defendant's] unapproved product exceed FDA standards; and failing to inform customers of the much lower aluminum content of [the Plaintiff's] approved product. [Id.].

[29] [30] To state a claim for false advertising under the Lanham Act, a plaintiff must allege that: (1) the defendant made a false or misleading description of fact or representation of fact in a commercial advertisement; (2) the misrepresentation is material, in that it is likely to influence the purchasing decision; (3) the misrepresentation actually deceives or has the tendency to deceive a substantial segment of its audience; (4) the defendant placed the false or misleading statement in interstate commerce; and (5) the plaintiff has been or is likely to be injured as a result of the misrepresentation, either by direct diversion of sales or by a lessening of goodwill associated with their product. Scotts Co. v. United Indus. Corp., 315 F.3d 264, 272 (4th Cir. 2002). Unless the omission of a statement would render an affirmative statement false or misleading, the Lanham Act "imposes no affirmative duty of disclosure." MDM Grp. Assocs., Inc. v. Emerald Isle Realty, Inc., No. 2:07-CV-48 D, 2008 WL 2641271, at \*5 (E.D.N.C. July 1, 2008) (citation and quotations omitted); see also Casper Sleep, Inc. v. Mitcham, 204 F. Supp. 3d 632, 638 (S.D.N.Y. 2016).

#### 1. Failing to Update Dear Healthcare Provider Letter

\*\*16 [31] The Plaintiff asserts that the Defendant violated the Lanham Act by continuing to send Dear Healthcare Provider letters stating that "there are currently no FDA-approved L-Cysteine Hydrochloride Injection products in the United States" even after ELCYS received FDA approval on April 16, 2019. [Doc. 1 at ¶ 41; Doc. 1-18; see also Doc. 31-2 at 41-59]. The Plaintiff does, however, allege that the Defendant updated its customers on September 25, 2019, when it told them that "there is \*1024 now an FDA approved L-Cysteine available in the US market." [Doc. 1-21 at 2]. <sup>14</sup> The Defendant moves to dismiss, arguing that the Plaintiff's Lanham Act claims fail as a matter of law. [Doc. 29-1 at 16-32].

While the Defendant argues that the Dear Healthcare Provider letters do not constitute commercial advertising, another court has held that Dear Healthcare Provider letters are "disseminated in a manner sufficient to constitute commercial advertising placed in interstate commerce[.]" De Simone v. VSL Pharm., Inc., 395 F. Supp. 3d 617, 624 (D. Md. 2019).

In <u>POM Wonderful LLC v. Coca–Cola Co.</u>, the Supreme Court held that "the FDCA and the Lanham Act complement each other" and the FDCA does not categorically bar Lanham

Act suits. 573 U.S. 102, 134 S. Ct. 2228, 2241, 189 L.Ed.2d 141 (2014). POM Wonderful, nevertheless, preserved "the possibility that some Lanham Act suits might be precluded by the FDCA." JHP Pharm., LLC v. Hospira, Inc., 52 F. Supp. 3d 992, 998 (C.D. Cal. 2014) (citing id.). Specifically, the Court in POM Wonderful said that a Lanham Act claim may be precluded by the FDCA if "it turns on the content" of something that has been "previously preapproved by the FDA." Id. at 998; see also Church & Dwight Co. Inc. v. SPD Swiss Precision Diagnostics, GmbH, 104 F. Supp. 3d 348, 352 (S.D.N.Y. 2015) (stating POM Wonderful held that "in essence, that Lanham Act claims might be precluded if the FDA had authorized the challenged name and label."). Moreover, POM Wonderful suggested that a Lanham Act claim might be precluded by the FDCA if it conflicts "with an affirmative policy judgment by the FDA." JHP Pharm. 52 F. Supp. 3d at 998 (citing POM Wonderful, 134 S. Ct. at 2241). Likewise, other courts have found that Lanham Act claims which "involve an issue on which the FDA has taken 'positive regulatory action' are all likely precluded by the FDCA." Allergan USA Inc. v. Imprimis Pharm., Inc., No. SACV171551DOCJDEX, 2017 WL 10526121, at \*7 (C.D. Cal. Nov. 14, 2017) (quoting JHP Pharm., 52 F. Supp. 3d at 1000 n.5, 1004).

Here, the Plaintiff's Lanham Act claim regarding the Dear Healthcare Provider letters "turns on the content" of something that was "previously preapproved by the FDA." JHP Pharm., 52 F. Supp. 3d at 998. Because the Plaintiff's Lanham Act claim challenges the letters that were a condition of the Memorandum of Discretion, it thereby also challenges the FDA's policy judgment and implicates an issue upon which the FDA has taken positive regulatory action. Imprimis Pharm., 2017 WL 10526121, at \*7. Based on the Supreme Court's discussion in POM Wonderful, such a claim is precluded.

Examining the practical effects of allowing such a claim to proceed further demonstrates that preclusion is appropriate here. If the Plaintiff were correct that the FDA approved and mandated Dear Healthcare Provider letters could serve as the grounds for a Lanham Act violation, the Defendant would have had three options once ELCYS received FDA approval in April 2019: (1) face Lanham Act liability for continuing to distribute its L-Cysteine product with the FDA-approved Dear Healthcare Provider letter; (2) face FDA enforcement action for violating the Memorandum of Discretion by sending a new Dear Healthcare Provider letter that had not been approved by the FDA; or (3) withdraw

its product from the market completely while it negotiated a new Dear Healthcare Provider letter with the FDA. It is unreasonable to interpret the Lanham Act to impose such a Hobson's choice, particularly when the FDA has taken and continues to take positive regulatory action \*1025 to address something as critical and sensitive as a drug shortage. As such, this is not an instance where "the FDCA and the Lanham Act complement each other ...." POM Wonderful, 573 U.S. 102, 134 S. Ct. 2228, 2241, 189 L.Ed.2d 141 (2014). Accordingly, the Plaintiff's Lanham Act claim based on the Defendant's failure to send a new Dear Healthcare Provider letter after ELCYS received FDA approval fails to state a claim upon which relief can be granted.

#### 2. Failing to Disclose Aluminum Content Difference

\*\*17 [32] The Plaintiff's Lanham Act claim also fails to the extent it is based on the Defendant's failure to affirmatively advertise the aluminum content of its L-Cysteine product. The Plaintiff, however, concedes that the Defendant never affirmatively "told its customers the respective aluminum levels of the [Plaintiff and the Defendant's] products." [Doc. 1 at ¶ 9]. The Plaintiff makes no allegation that the Defendant made any statement that would be rendered false or misleading by failing to affirmatively provide information regarding its product's aluminum content or ELCYS's aluminum content. The Defendant had no duty to provide such a statement under the Lanham Act. Therefore, the Plaintiff cannot state a Lanham Act claim based on the Defendant's failure to affirmatively advertise the difference between the aluminum content in its L-Cysteine product and ELCYS. Emerald Isle Realty, 2008 WL 2641271, at \*5; see also Casper Sleep, 204 F. Supp. 3d at 638.

#### 3. Failing to Disclose FDA "Standards"

The Plaintiff also asserts that the Defendant failed to inform customers that the aluminum levels of its "unapproved product exceed FDA standards." [Doc. 1 at ¶ 84]. What the Plaintiff refers to as FDA "standards," however, are not actual FDA standards at all. (See, Part IV.A.1.c., <u>supra.</u>). As such, Plaintiff's allegations are based on a false premise. Moreover, the Plaintiff's own allegations show that the Defendant never made any statement regarding the aluminum content of its L-Cysteine product or whether its product met any FDA "standards." The Lanham Act "imposes no affirmative duty

of disclosure." Emerald Isle Realty, 2008 WL 2641271, at \*5; Casper Sleep, 204 F. Supp. 3d at 638.

This claim is a thinly veiled attempt by the Plaintiff to step into the shoes of the FDA to enforce the FDCA based on an underlying assumption that the Defendant's product is unsafe due to its aluminum levels. Such a claim is precluded. PhotoMedex, Inc. v. Irwin, 601 F.3d 919, 924 (9th Cir. 2010) ("Because the FDCA forbids private rights of action under that statute, a private action brought under the Lanham Act may not be pursued when, as here, the claim would require litigation of the alleged underlying FDCA violation in a circumstance where the FDA has not itself concluded that there was such a violation."); American Home Products Corp. v. Johnson & Johnson, 436 F. Supp. 785, 797 (S.D.N.Y. 1977) (stating that "an action under the Lanham Act and state unfair competition laws is not the proper legal vehicle in which to vindicate the public's interest in health and safety."). Accordingly, the Plaintiff's Lanham Act claim cannot be based on the Defendant's failure to disclose that its product does not meet FDA "standards."

For all these reasons, the Plaintiff's Lanham Act claim will be dismissed.

#### V. CONCLUSION

In 2014 the FDA determined that there was a shortage of L-Cysteine product needed for medical treatments in the United States. The FDA approached the Defendant \*1026 and worked out a program to *temporarily* allow the Defendant to import and sell its L-Cysteine product in the United States

to meet this shortage. The Plaintiff meanwhile developed a competing L-Cysteine product for which the Plaintiff sought full FDA approval to sell in the U.S. market. Regarding the brief (less than six-month) period of the overlap of the availability of both the Plaintiff's and the Defendant's product, the Plaintiff complains that the FDA should not have allowed the Defendant to continue to sell its product. The Plaintiff brings this action, however, against the Defendant, not the FDA. Because of the exclusivity of the FDCA and the authority of the FDA regarding such sales, the Plaintiff's claims against the Defendant fail both under the Lanham Act and pursuant to state law. For this reason, the Defendant's Motion to Dismiss will be granted.

#### **ORDER**

IT IS, THEREFORE, ORDERED that the Defendant's Motion to Dismiss the Complaint or, in the Alternative, Stay the Case Pending Referral to FDA [Doc. 29] is GRANTED, and this action is DISMISSED WITH PREJUDICE.

\*\*18 IT IS FURTHER ORDERED that the Plaintiff's Motion for Preliminary Injunction [Doc. 3] is **DENIED**.

The Clerk of Court is directed to close this civil action.

IT IS SO ORDERED.

**All Citations** 

486 F.Supp.3d 1001, 2020 WL 5535026

**End of Document** 

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## **Tab 10**

199 Fed.Appx. 90
This case was not selected for publication in West's Federal Reporter.
See Fed. Rule of Appellate Procedure 32.1 generally governing citation of judicial decisions issued on or after Jan. 1, 2007. See also U.S.Ct. of Appeals 3rd Cir. App. I, IOP 5.1, 5.3, and 5.7.
United States Court of Appeals,
Third Circuit.

James E. FOSTER, Appellant v.

JLG INDUSTRIES, INC.; Mr. Clifford B. Geiger; Mr. Duane Souders, Manager, JLG; Eugene Swope, Manager, JLG; Samuel Swope, V.P. Human Resources, JLG; Jeanne Wakefield, Human Resources, JLG; Kollman & Saucier; Frank Kollman; Peter Saucier.

No. 06–1537. | Submitted Under Third Circuit LAR 34.1(a) Sept. 22, 2006. | Filed: Oct. 4, 2006.

#### **Synopsis**

**Background:** Terminated employee brought pro se action against employer, its officials, and its attorney, asserting claims under Title VII and Age Discrimination in Employment Act (ADEA), as well as state claims for fraud, defamation, and intentional infliction of emotional distress. The United States District Court for the Middle District of Pennsylvania, Sylvia H. Rambo, J., 2006 WL 223899, granted judgment for defendants. Plaintiff appealed.

**Holdings:** The Court of Appeals held that:

- [1] amendment of § 1983 claim would have been futile;
- [2] former employee had to allege cognizable federal violation that could have formed basis of civil conspiracy in order to state claim under § 1985;

- [3] allowing amendment would have caused undue delay and undue prejudice to opposing party;
- [4] employee did not state cognizable claim for defamation;
- [5] employee's Title VII claim was unexhausted;
- [6] employee did not demonstrate prima facie case of retaliation;
- [7] district court did not abuse its discretion by denying employee's motion for extension of time to file motion to compel depositions; and
- [8] ordering employee to provide witness list prior to pretrial conference was not abuse of discretion.

Affirmed.

West Headnotes (8)

### [1] Federal Civil Procedure Form and sufficiency of amendment; futility

Amendment of § 1983 claim against corporate employer, its officials, and its attorney would have been futile, since defendants were private actors. 42 U.S.C.A. § 1983; Fed.Rules Civ.Proc.Rule 15(a), 28 U.S.C.A.

[2] Conspiracy Existence of independent claim; necessity of and relationship to underlying right or violation

In order to state claim under § 1985, former employee had to allege cognizable federal violation that could have formed basis of civil conspiracy. 42 U.S.C.A. § 1985.

### [3] Federal Civil Procedure Fime for amendment

Allowing amendment would have caused undue delay and undue prejudice to opposing party, and thus district court did not abuse its discretion in denying leave to amend, where court had provided pro se plaintiff with ample opportunities to amend in one and one-half year that action had been pending and most recent amended complaint was plaintiff's fourth attempt at amended complaint. Fed.Rules Civ.Proc.Rule 15(a), 28 U.S.C.A.

#### [4] Libel and Slander 🕪 Employees

Former employee did not state cognizable claim for defamation under Pennsylvania law against corporate employer, its officials, and its attorney on allegations that defendants defamed him when they opposed his claim for unemployment benefits by representing that he had sexually harassed female co-worker and referee for Pennsylvania Unemployment Compensation Board of Review determined that "he is an Identifiable Victim."

## [5] Civil Rights Exhaustion of state or local remedies

Former employee's Title VII claim against employer, its officials, and its attorney, which alleged that he was terminated based on his reports to his employer of sexual harassment of other co-workers, was unexhausted, where complaints that employee filed with state agency alleged that employer terminated employee because of his age and defendants later retaliated against him for filing complaint by giving negative employment references. Civil Rights Act of 1964, § 703, 42 U.S.C.A. § 2000e–2.

#### [6] Evidence - As to particular facts in general

Former employee did not demonstrate prima facie case of retaliation under ADEA on his claim that, after he filed age discrimination claim with state agency, employer retaliated against him by failing to provide positive employment references for him, where employee admitted that he believed that employer had terminated him because of personal vendettas against him, none of which involved age. Age Discrimination

in Employment Act of 1967, § 4(d), 29 U.S.C.A. § 623(d).

3 Cases that cite this headnote

## [7] Federal Civil Procedure Order compelling answer

District court did not abuse its discretion by denying party's motion for extension of time to file motion to compel depositions, where party had sought to depose two witnesses, who refused to appear unless compelled by valid subpoenas, but did not personally serve subpoenas, properly sign them, or include required witness fee and mileage, case had been ongoing for approximately two years, and party sought to compel information that was irrelevant to his case.

2 Cases that cite this headnote

### [8] Federal Civil Procedure 🕪 Identity and

location of witnesses and others

Federal Civil Procedure 🤛 Scope

Ordering a litigant to provide a witness list prior to a pretrial conference is not an abuse of discretion. Fed.Rules Civ.Proc.Rule 16(c), 28 U.S.C.A.

\*91 On Appeal from the United States District Court for the Middle District of Pennsylvania (D.C. Civ. No. 03–cv–2088), Honorable Sylvia H. Rambo, District Judge.

#### **Attorneys and Law Firms**

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Thomas B. Sponaugle, Griffith, Strickler, Lerman, Solymos & Calkins, York, PA, Clifford B. Geiger, Kollman & Saucier, Baltimore, MD, for Appellees.

Before: FISHER, ALDISERT and WEIS, Circuit Judges.

**OPINION** 

#### PER CURIAM.

- \*\*1 James E. Foster appeals the orders of the United States District Court for the Middle District of Pennsylvania awarding judgment to the defendants in his lawsuit. In February 2005, Foster filed a third amended complaint against JLG Industries, Inc., four of its employees, the law firm representing JLG, and three of the law firm's attorneys. Foster alleged civil rights violations under 42 U.S.C. §§ 1983 and 2000e-(3), civil conspiracy in violation of 42 U.S.C. § 1985, retaliation in violation \*92 of 29 U.S.C. § 623(d), and state tort law claims including defamation, fraud, and intentional infliction of emotional distress.<sup>2</sup> He maintains that the district court erred in dismissing all claims except one (the Age Discrimination in Employment Act ("ADEA") (29 U.S.C. § 623(d)) claim against JLG), and erred by later granting summary judgment to JLG on the ADEA claim. He further contends that the district court abused its discretion when it denied his motion for extension of time to compel depositions and that it improperly required him to turn over his witness list prior to a pre-trial conference. Finding no error with the district court's actions, we will affirm.
- Foster filed his initial complaint in November 2003. When he sought to amend it, the district court provided Foster with several opportunities to file an amended complaint that would comport with federal and local rules and the district court's orders.
- In his appellate brief, Foster claims that he wants the law for "forgery" to be applied to his case, however, Foster did not assert a forgery claim in his third amended complaint and we need not consider what, if any, applicability such law would have to his case.

#### I. Dismissal of claims on June 6, 2005

After the defendants moved to dismiss all claims, the district court dismissed Foster's claims under § 1983, § 1985 and Title VII, and his claims for fraud, intentional infliction of emotional distress and defamation. We agree with the district court's assessment and dismissal of these claims.

[1] [2] Prior to Foster's filing a third amended complaint, the district court issued an order on December 21, 2004, specifically identifying certain claims that it would permit Foster to file in a third amended complaint. The court had previously rejected Foster's §§ 1983 and 1985 claims, and so it did not permit Foster to re-file these claims. To permit amendment of these claims would have been futile, first,

because Foster sued entirely private actors—he named no state actors as defendants such that a § 1983 claim might lie. Also, Foster alleged no cognizable federal violation that could form the basis of civil conspiracy under § 1985. The district court correctly dismissed these claims in its June 6, 2005 order.

- In addition, the district court's December 2004 order did not grant Foster leave to file claims for fraud or intentional infliction of emotional distress. Foster's third amended complaint containing these claims was, therefore, appropriately restricted by the district court. Under Fed. Rule of Civ. P. 15(a), litigants should be granted leave to amend "when justice so requires." However, there are reasons to curtail or deny a request for leave to amend, including where, such as here, there is "repeated failure to cure deficiencies by amendments previously allowed" and there would be "futility of amendment." Foman v. Davis, 371 U.S. 178, 182, 83 S.Ct. 227, 9 L.Ed.2d 222 (1962). The district court had provided Foster with ample opportunities to amend in the year and a half that Foster's action had been pending; the third amended complaint was Foster's fourth attempt at an amended complaint. The court also wisely determined that these latest amendments also would have caused undue delay and "undue prejudice to the opposing party by virtue of allowance of the amendment." Id.<sup>3</sup>
- We also agree with the district court that Foster failed to state a claim on either the fraud or intentional infliction of emotional distress claims. As noted in the district court's memorandum opinion, this Court has opined how "extremely rare" it is "to find conduct in the employment context that will rise to the level of outrageousness necessary" for a claim of intentional infliction of emotional distress. *Cox v. Keystone Carbon*, 861 F.2d 390, 395 (3d Cir.1988). Additionally, Foster's fraud claim fell far short of the specificity required for allegations of fraud. *See* Fed. R. Civ. P. 9(b).
- \*93 \*\*2 [4] As for his defamation claim, Foster asserted that the defendants (several or all of them) defamed him when they opposed his claim for unemployment benefits by representing that he had sexually harassed a female co-worker. Foster was initially denied benefits, but the Pennsylvania Unemployment Compensation Board of Review ("PUCBR") reversed that decision on appeal because the sexual harassment allegations were based upon hearsay. Foster need not have proved his defamation claim in the pleadings stage, but his allegations in the complaint on this charge could hardly be deemed enough to overcome

a motion to dismiss: in the defamation count, Foster merely states that "he is an Identifiable Victim" and that "[t]his determination is supported by the Pennsylvania Unemployment Compensation Board of Review—Referee's Decision." But these statements alone do not assert a viable defamation claim against the numerous defendants named in this action, even affording the complaint wide latitude.<sup>4</sup>

- Alternatively, the statements made to the PUCBR (or to the Pennsylvania Human Relations Commission ("PHRC"), as suggested in Foster's brief on appeal) would likely be considered privileged by Pennsylvania courts because proceedings before these bodies are quasi-judicial in character. See Milliner v. Enck, 709 A.2d 417, 419 n. 1 (Pa.Super.Ct.1998); see also Giusto v. Ashland Chemical Co., 994 F.Supp. 587, 593–94 (E.D.Pa.1998) (holding that PHRC proceedings are quasi-judicial and statements made in the normal course of those proceedings are absolutely privileged).
- [5] The district court also dismissed Foster's Title VII claim. Foster maintained that the defendants violated Title VII by retaliating against him for filing an ADEA claim, reporting leakage of hazardous waste, and reporting sexual harassment of other coworkers to his employer in late 1995. Neither of the first two claims falls within the purview of Title VII, which prohibits discrimination based upon race, color, religion, sex or national origin. See 42 U.S.C. § 2000e–2.
- We address below Foster's claim that he was retaliated against under the ADEA. Foster did not raise any issue regarding retaliation for reporting hazardous waste in his brief on appeal.

More to the point, the district court correctly noted that Foster's claim based on the sexual harassment complaints was unexhausted. Foster's two complaints filed with the PHRC (one in 1997 and another in 2001) do not allege that he was terminated because he reported sexual harassment of other co-workers. Rather, they allege, respectively, that JLG terminated Foster because of his age, and that defendants later retaliated against him for filing the first Pennsylvania Human Relations Act ("PHRA") complaint by giving negative employment references. A Title VII claimant must exhaust administrative remedies prior to seeking relief in federal court. "A complaint does not state a claim upon which relief may be granted unless it asserts the satisfaction of the precondition to the suit specified by Title VII: prior submission of the claim to the EEOC or conciliation or resolution." Robinson v. Dalton, 107 F.3d 1018, 1022 (3d Cir.1997) (internal quotations omitted). Foster did not demonstrate that he exhausted this claim with the EEOC.

- II. Grant of Summary Judgment to JLG<sup>6</sup> on ADEA Retaliation Claim on January 30, 2006
- In an order entered on June 16, 2005, the district court clarified that the only remaining defendant after the June 6 dismissal order was JLG. The court's December 21, 2004 order had limited Foster to filing an ADEA claim against JLG only, since the additional defendants were not individually liable under the ADEA. See Violanti v. Emery Worldwide A-CF Co., 847 F.Supp. 1251, 1257 (M.D.Pa.1994).
- [6] Foster alleged that, after he filed an age discrimination claim with the \*94 PHRC, JLG retaliated against him by failing to provide positive employment references for him. The district court correctly disposed of this claim because Foster failed to demonstrate a prima facie case of retaliation under the *McDonnell Douglas* framework, namely: (1) that he engaged in a protected activity; (2) that he was subject to adverse action by the employer either subsequent to or contemporaneous with the protected activity; and (3) that there was a causal connection between the protected activity and the adverse action. *Fasold v. Justice*, 409 F.3d 178, 188 (3d Cir.2005) (noting that in the absence of direct evidence of retaliation, retaliation claims under the ADEA and the PHRA ordinarily proceed under the *McDonnell Douglas* framework).
- In his amended complaint, Foster also alleged that he was terminated in retaliation for filing the age discrimination complaint with the PHRC. Considering that Foster was terminated on January 20, 1997, and he filed his complaint in the PHRC on January 24, 1997, the district court correctly dismissed this part of Foster's ADEA claim on June 6, 2005, because "it would have been impossible for Defendants to retaliate against an action that had not already occurred." 372 F.Supp.2d 792, 803 (M.D.Pa.2005).
- \*\*3 Foster made a series of damaging admissions with respect to this claim, as highlighted by the district court in its January 30, 2006, opinion. See District Court 1/30/06 Opinion, 2006 WL 223899, at 6–7. Specifically, Foster admitted at his deposition that he believed that JLG had terminated him because of personal vendettas against him, none of which involved age. Foster further stated that the theory he had been terminated for age was the view of his former attorney, and that he did not share that view. He also

admitted to a JLG Vice President that age discrimination "had nothing to do" with his filing of the PHRA complaint, but that he needed to file something because he did not have insurance.

Like another case decided by this Court in which the retaliation claimant made damaging admissions under oath, we find that "[h]is own words under oath completely preclude him from establishing the third of the three prongs necessary to prevail in a retaliation case." *Glanzman v. Metro*. Management Corp., 391 F.3d 506, 511 (3d Cir.2004). Stated otherwise, Foster could not establish causation even if he had produced some evidence of an adverse action, which he did not. Furthermore, the district court rightly determined that Foster's statements belied that he had a good faith, reasonable belief when he pursued the age discrimination claim with the PHRC. See Aman v. Cort Furniture Rental Co., 85 F.3d 1074, 1085 (3d Cir.1996) ("A plaintiff need not prove the merits of the underlying discrimination complaint, but only that he was acting under a good faith, reasonable belief that a violation existed."). The district court's order granting summary judgment to JLG was well-justified.

III. Denial of Motion for Extension of Time to File a Motion to Compel Depositions

[7] Months after the district court dismissed all claims except for the ADEA claim against JLG, Foster filed a motion for an extension of time to file a motion to compel depositions. The district court denied it on November 18, 2005. Foster had sought to depose two witnesses (who refused to appear unless compelled to by valid subpoenas) but failed to personally serve the subpoenas, properly sign them, and to include the required witness fee and mileage.

We discern no abuse of discretion with respect to the denial of Foster's discovery \*95 motion. *Petrucelli v. Bohringer and Ratzinger*, 46 F.3d 1298, 1310 (3d Cir.1995) (applying abuse of discretion standard "when reviewing orders regarding the scope and conduct of discovery"). Contrary to Foster's assertions, the required criteria for subpoenas were not "mere technicalities" used to deny Foster the extension; in addition to the fact that the subpoenas were invalid, Foster apparently sought to compel information that was irrelevant to the sole remaining claim in the case, the ADEA claim. We would also point out that Foster's case had been pending since November 2003, and the case had been ongoing for approximately two years. The district court's denial of the motion was entirely reasonable.

\*\*4 [8] Finally, in his appellate brief, Foster states that the district court required him to submit a witness list prior to a pretrial conference. He does not identify any specific order related to this contention, nor does he elaborate further on this claim. We would simply note that the district court has discretion to manage its caseload, and, within those duties, Federal Rule of Civil Procedure 16(c) notes that at any pretrial conference, the court may consider and take appropriate action with respect to "the avoidance of unnecessary proof and cumulative evidence, and limitations or restrictions on the use of testimony under Rule 702 of the Federal Rules of Evidence," and "the identification of witnesses and documents." Id. at (4) and (7). Ordering a litigant to provide a witness list prior to a pretrial conference is *not* an abuse of discretion. It is entirely in accordance with the federal rules and is often a necessary requirement in order for district courts to manage cases effectively.

#### **All Citations**

199 Fed.Appx. 90, 2006 WL 2846264

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# Tab 11

2013 WL 4508003 Only the Westlaw citation is currently available. United States District Court, E.D. Louisiana.

Jacob GUILLOT, et al.
v.
AVENTIS PASTEUR, INC., et al.

Civil Action No. 02–3373. | Aug. 22, 2013.

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#### ORDER AND REASONS

MARY ANN VIAL LEMMON, District Judge.

\*1 IT IS HEREBY ORDERED that Eli Lilly and Company's Motion for Judgment on the Pleadings (Doc. #49) is **GRANTED.** 

**IT IS FURTHER ORDERED** that Sanofi Pasteur Inc., Merck Sharpe & Dohme Corp. and GlasxoSmithKlien LLC's Motion to Dismiss (Doc. # 51) is **GRANTED.** 

**IT IS FURTHER ORDERED** that American International Chemical, Inc.'s Motion to Dismiss (Doc. # 55) is **GRANTED.**<sup>1</sup>

Due to this court's rulings on defendants' motions to dismiss and motion for judgment on the pleadings, it is unnecessary to rule on defendants' motions for summary judgment (Docs. #47, 50 and 53), and those motions are disposed of by this Order and Reasons.

**IT IS FURTHER ORDERED** that Plaintiffs' Motion to Strike (Doc. # 60) is **DENIED**.

IT IS FURTHER ORDERED that Plaintiffs' Motion for Leave to Supplement and Amend the Complaint (Doc. #81) is GRANTED as to bringing claims of Jacob Guillot under the Louisiana Products Liability Act ("LPLA"), Louisiana Revised Statutes § 9:2800.51, et seq., for failure to warn against Eli Lilly and Company, American International Chemical, and Spectrum Laboratory Products, Inc. (Count III of the Proposed Amended Complaint). The motion is DENIED as to asserting claims of Jacob under the LPLA for composition and construction, design defects and breach of warranty as to Eli Lilly and Company, American International Chemical, and Spectrum Laboratory Products, Inc. (Count III of the Proposed Amended Complaint), all proposed claims against Sanofi Pasteur Inc., Merck Sharpe & Dohme Corp. and GlasxoSmithKlien LLC's (Counts I through VIII of the Proposed Amended Complaint), and Counts I, II, and IV through VIII of the Proposed Amended Complaint against Eli Lilly and Company, American International Chemical, and Spectrum Laboratory Products, Inc.

#### BACKGROUND

On August 15, 2002, Plaintiffs, Dale and Angel Guillot filed this action on their own behalf and on behalf of their minor son, Jacob Guillot, in the Seventeenth Judicial District Court, Parish of Lafourche, State of Louisiana. On November 8, 2002, defendant, Eli Lilly and Company, with the consent of the other defendants, timely removed the action to the United States District Court for the Eastern District of Louisiana alleging diversity subject matter jurisdiction under 28 U.S.C. § 1332.

In the complaint, the plaintiffs allege that Jacob was injured by vaccines that contained Thimerosal, a mercury based preservative. Plaintiffs allege that GlaxoSmithKlien, LLC (f/k/a SmithKlien Beecham Corporation), Sanofi Pasteur Inc. (f/k/a Aventis Pasteur, Inc.), Merck Sharpe & Dohme Corp. (f/k/a Merck & Co., Inc.) (collectively "vaccine defendants") manufactured the vaccines Jacob received, and that American International Chemical Inc., Eli Lilly and Company and Spectrum Laboratory Products, Inc. (collectively "Thimerosal defendants") manufactured the Thimerosal that was a component part of those vaccines.

Plaintiffs allege that Jacob, who was born on February 16, 1998, developed normally until the age of eighteen months, but then he became withdrawn, unable to speak and unresponsive, and lost motor skills. Plaintiffs claim that Jacob's disabilities were caused by the accumulation of mercury in his body due to the vaccines. In Count I, plaintiffs seek to bring a class action for medical monitoring against all defendants. In Count II, plaintiffs seek an injunction preventing the vaccine defendants from selling vaccines containing Thimerosal. Counts III, V and VII allege claims of negligence, wanton reckless, and outrageous conduct, and breach of warranty for fitness for a specific purpose, respectively, against the vaccine defendants. Counts IV, VI, VIII and IX allege strict liability, intentional infliction of emotional distress, breach of express and implied warranty and civil battery against all defendants. Count X is a claim under the Louisiana Unfair Trade Practices and Consumer Protection Act ("LUTPA"), La.Rev.Stat. § 54:1404, et seq., against all defendants. Count XI is a claim for the parents' mental anguish, loss of consortium, and economic damages for medical and related expenses incurred on Jacob's behalf and Jacob's lost earnings or earning ability.

\*2 In 2003, GlaxoSmithKlien, Sanofi Pasteur, Merck, American International Chemical and Eli Lilly<sup>2</sup> moved to dismiss all of plaintiffs' claims that are covered by the National Childhood Vaccine Injury Act of 1986 ("Vaccine Act"), 42 U.S.C. § 300aa–1, et seq. (Counts III through X, and Count XI as to Dale and Angel Guillot's claims for economic damages for medical and related expenses incurred on Jacob's behalf and Jacob's lost earnings or earning ability), and to stay all remaining claims (Counts I and II, and Count XI as to Dale and Angel Guillot's mental anguish and loss of consortium claims), while plaintiffs pursued remedies in accordance with the Vaccine Act. At oral argument on the motions, plaintiffs' counsel indicated on the record that he did not oppose the court's granting the defendants' motions. On March 31, 2003, the court granted the defendants' motions, dismissing without prejudice Counts III through X, and Count XI as to Dale and Angel Guillot's claims for economic damages for medical and related expenses incurred on Jacob's behalf and for Jacob's lost earnings or earning ability, and staying the remaining claims pending plaintiffs' pursuit of compensation remedies in the United States Court of Federal Claims under the Vaccine Act.

2 Spectrum has not filed any motions. However, plaintiffs' claims against Spectrum will be addressed collectively with plaintiffs' claims against the other defendants.

On April 14, 2003, plaintiffs filed a petition in the Vaccine Court. On March 8, 2012, the special master dismissed plaintiffs' case for failure to prosecute. Judgment was entered on April 11, 2012. Thereafter plaintiffs filed a Motion for Relief from Judgment pursuant to Rule 60(b) of the Rules of the United States Court of Federal Claims<sup>3</sup> and Rule 39 of the Vaccine Rules of the United States Court of Federal Claims.<sup>4</sup> On August 15, 2012, the special master denied plaintiffs' motion, noting that plaintiffs' petition in the Vaccine Court was untimely. Plaintiffs filed a motion for reconsideration, which the special master denied on September 13, 2012. On November 5, 2012, plaintiffs filed an election to proceed with a civil action, thereby purportedly giving them the ability to file a civil action for Jacob's vaccine-related injuries in this

- 3 Rule 60(b) of the Rules of the United States Court of Federal Claims is identical to Rule 60(b) of the Federal Rules of Civil Procedure.
- Rule 39 dictates whether a motion for relief from judgment filed under Rule 60 of the Rules of the United States Court of Federal Claims is handled by a judge of the United States Court of Federal Claims or the special master. In this case, the motion was referred to the special master under Rule 39.

On January 16, 2013, Sanofi Pasteur moved this court to reopen this case, arguing that the Vaccine Court "dismissed plaintiffs' claims for failure to prosecute and for insufficient proof, and because such claims were found to be time barred." Sanofi Pasteur requested a status conference to discuss whether plaintiffs intend to prosecute the case or dismiss their remaining claims in light of the Vaccine Court's rulings.

At the telephone status conference, plaintiffs' counsel indicated that plaintiffs intended to pursue their remaining claims. The court set dates for the defendants to submit motions to dismiss and motions for summary judgment to address preliminary legal questions before the parties engaged in potentially unnecessary discovery.

GlaxoSmithKlien, American International, Sanofi Pasteur and Merck filed motions to dismiss and motions for summary judgment. Eli Lilly filed a motion for judgment on the pleadings and a motion for summary judgment. Thereafter, plaintiffs filed a motion to continue the motions for summary

judgment, arguing that they needed to engage in discovery to adequately respond to the motions. This court denied plaintiffs' motion, noting that the plaintiffs could assert such arguments in opposition to the motions for summary judgment. Plaintiffs also filed a motion to strike documents related to the Vaccine Court and all mention of the Vaccine Court from defendants' motions to dismiss and motions for summary judgment.

\*3 Thereafter, the court noted that, in their motions, defendants address the claims asserted by plaintiffs in Counts III through XI of the complaint, which were dismissed without prejudice on March 31, 2003, pursuant to plaintiffs' agreement. "A dismissal without prejudice is a dismissal that occurs without an adjudication on the merits. The dismissal of an action without prejudice leaves the parties as though the action had never been brought." Graves v. Principi, 294 F.3d 1350, 1356 (Fed.Cir.2002) (citing Bonneville Assocs. Ltd. P'ship v. Barram, 165 F.3d 1360, 1364 (Fed.Cir.1999) (stating that "[t]he rule in federal courts is that '[t]he effect of a voluntary dismissal without prejudice ... is to render the proceedings a nullity and leave the parties as if the action had never been brought' "); see also 9 Charles Alan Wright & Arthur R. Miller, Federal Practice and Procedure § 2367 (3d ed.2008). Thus, Counts III through X, and Count XI as to Dale and Angel Guillot's claims for economic damages for medical and related expenses incurred on Jacob's behalf and for Jacob's lost earnings or earning ability are not before the court.

On May 1, 2013, plaintiffs moved to amend the complaint to assert the claims that were not properly before the court at the time the defendants' filed their motions. In the Proposed Amended Complaint, plaintiffs reassert their claims for a medical monitoring class action, an injunction and the parents' loss of consortium and mental anguish. They also seek to bring claims under the LPLA, LUTPA, redhibition and breach of warranty. Further, they seek damages for the parents' economic damages for medical and related expenses incurred on Jacob's behalf and for Jacob's lost earnings or earning ability. Defendants oppose plaintiffs' motion to amend the complaint.

In the Proposed Amended Complaint, plaintiffs do not specifically seek to re-allege the following claims that were included in the complaint and dismissed without prejudice by consent: negligence and wanton, reckless, and outrageous conduct against the vaccine defendants; and, strict liability, intentional infliction of emotional

distress and civil battery against all defendants. As discussed herein, these tort claims are not available against these manufacturer defendants due to the LPLA's exclusivity provision. *See* La.Rev.Stat. § 9:2800.52; *see also Jefferson v. Lead Indus. Ass'n, Inc.*, 106 F.3d 1245, 1251 (5th Cir.1997).

#### **ANALYSIS**

#### I. Plaintiffs' Motion to Strike

Plaintiffs seek to strike mention of the Vaccine Court from defendants' motions to dismiss and motions for summary judgment. Plaintiffs argue that all such mention should be eliminated because the Vaccine Act does not permit the rulings of the Vaccine Court to be used as evidence in subsequent litigation involving the vaccine-related injury.

Title 42, United States Code, Section 300aa–23(e) "Evidence," provides:

In any stage of a civil action, the Vaccine Injury Table, any finding of fact or conclusion of law of the United States Court of Federal Claims or a special master in a proceeding on a petition filed under section 300aa–11 of this title and the final judgment of the United States Court of Federal Claims and subsequent appellate review on such a petition shall not be admissible.

42 U.S.C. § 300aa–23(e). The Vaccine Act includes this section to prevent confusion in a civil action because the proceedings in the Vaccine Court are fundamentally different from traditional civil actions. The House Report on the Vaccine Act explains:

Compensation standards, evidence, and proceedings are sufficiently different from civil proceedings in tort that the findings made in compensation are not likely to be based on the more rigorous requirements of tort proceedings and might confuse such civil action.

\*4 H. Rep. 908, 99th Cong., 2d Sess. 1, 29, reprinted in 1986 U.S. C.C.A.N. 6344, 6370. Section 300aa–23(e) prohibits the introduction into evidence in a civil tort suit of the Vaccine Injury Table and findings of fact or conclusions of law and judgments in the Vaccine Court's proceedings. It does not prohibit the court from considering the fact of the Vaccine Court proceedings to determine whether plaintiffs complied with the Vaccine Act's prerequisites to filing a civil tort suit. See 42 U.S.C. § 300aa–1, et seq.

This court will not consider the prohibited items as evidence in determining liability, but will consider the existence of

the record in the Vaccine Court for the appropriate purposes. Thus, plaintiffs' motion to strike is DENIED.

### II. Defendants' Motions to Dismiss Counts I and II of the Complaint (Docs. # 49, 51 & 55)

Defendants argue that this court lacks subject matter jurisdiction over plaintiffs' class action claim for medical monitoring and claim against the vaccine defendants for an injunction because plaintiffs do not have standing to assert such claims.

#### A. Rule 12(b)(1) of the Federal Rules of Civil Procedure

"Motions filed under Rule 12(b)(1) of the Federal Rules of Civil Procedure allow a party to challenge the subject matter jurisdiction of the district court to hear a case." *Ramming v. United States*, 281 F.3d 158, 161 (5th Cir.2001) (citing Fed.R.Civ.P. 12(b)(1)). "Lack of subject matter jurisdiction may be found in any one of three instances: (1) the complaint alone; (2) the complaint supplemented by undisputed facts evidenced in the record; or (3) the complaint supplemented by undisputed facts plus the court's resolution of disputed facts." *Id.* (citing *Barrera–Montenegro v. United States*, 74 F.3d 657, 659 (5th Cir.1996)). If the defendant attacks the facts on which the court's subject-matter jurisdiction rests, the court is "free to weigh the evidence and satisfy itself as to the existence of its power to hear the case." *Arena v. Graybar Elec. Co., Inc.*, 669 F.3d 214, 223 (5th Cir.2012).

In a 12(b)(1) motion, the party asserting jurisdiction bears the burden of proving that jurisdiction does in fact exist. *Ramming*, 281 F.3d at 161. "The plaintiff must prove by a preponderance of the evidence that the court has jurisdiction based on the complaint and evidence." *Ballew v. Cont'l Airlines, Inc.*, 668 F.3d 777, 781 (5th Cir.2012) (citing *Paterson v. Weinberger*, 644 F.2d 521, 523 (5th Cir.1981)). However, "[a] Rule 12(b)(1) motion 'should be granted only if it appears certain that the plaintiff cannot prove a plausible set of facts that establish subject-matter jurisdiction.' "*Battaglia*, 495 Fed. Appx. at 441 (quoting *Castro v. United States*, 560 F.3d 381, 386 (5th Cir.2008)).

#### **B.** Standing

Under Article III of the Constitution of the United States, a litigant must have "'standing' to invoke the power of the federal court." *Allen v. Wright*, 104 S.Ct. 3315, 3324 (1984). "'In essence the question of standing is whether the litigant is entitled to have the court decide the merits of

the dispute or of a particular issue.' " *Id.* (quoting *Warth v. Seldin, 95 S.Ct. 2197, 2205 (1975)*). The party seeking to have claims redressed by the federal court must establish the elements of standing for each claim that he seeks to press. *Lujan v. Defenders of Wildlife, 112 S.Ct. 2130, 2136 (1992); DaimlerChrysler Corp. v. Cuno, 126 S.Ct. 1854, 1867 (2006).* Absent Article III standing, a federal court does not have subject matter jurisdiction to address a plaintiff's claims, and the claim must be dismissed. U.S. Constitution Art. 3, § 2, cl. 1.

\*5 Standing has constitutional and prudential requirements. Standing, at its "irreducible constitutional minimum," requires a plaintiff to demonstrate that: (1) he has suffered an "injury-in-fact"; (2) the injury is fairly traceable to the defendant's actions; and (3) that the injury will likely be redressed by a favorable decision. *Lujan*, 112 S.Ct. at 2136. An "injury-in-fact" is "an invasion of a legally protected interest which is (a) concrete and particularized, and (b) actual or imminent, not conjectural or hypothetical." *Webb v. City of Dall.*, *Tex.*, 314 F.3d 787, 791 (5th Cir.2002).

### 1. Purported Class Action for Medical Monitoring (Count I)

Defendants argue that the plaintiffs cannot maintain a class action for medical monitoring because Jacob is not an appropriate class representative.

#### a. Class Action

Pursuant to Rule 23 of the Federal Rules of Civil Procedure, a class member may sue as a representative party on behalf of all class members if:

- (1) the class is so numerous that joinder of all members is impracticable;
- (2) there are questions of law or fact common to the class;
- (3) the claims or defenses of the representative parties are typical of the claims or defenses of the class; and
- (4) the representative parties will fairly and adequately protect the interests of the class.

Fed.R.Civ.P. 23(a). To having standing to pursue a class action, the named plaintiff purporting to represent the class must establish a case or controversy with the defendants, otherwise he may not "seek relief on behalf of himself or any other members of the class." *O'Shea v. Littleton*, 94 S.Ct. 669, 675–76 (1974) (citations omitted).

If the factors set forth in Rule 23(a) are fulfilled and the named plaintiff has standing, a class action may be maintained if one of the categories provided in Rule 23(b) is satisfied. Fed.R.Civ.P. 23(b); see also 5 James Wm. Moore, et. al., Moore's Federal PracticeE § 23.40 (3d ed.2009). If monetary damages are the primary relief sought by a purported medical monitoring class, the standard of Rule 23(b)(3) must be satisfied. Zinser v. Accufix Research Institute, Inc., 253 F.3d 1180, 1195–96 (9th Cir. 2001). However, if the relief sought is a court-supervised program for periodic medical examination, Rule 23(b)(2) applies. Barnes v. Am. Tobacco Co., 161 F.3d 127, 132 (3rd Cir.1998).

In their purported class action for medical monitoring, plaintiffs primarily seek monetary damages of "funds for medical tests, treatment, periodic evaluations and the establishment of funds to be set aside for scientific research related to mercury neurotoxicity via vaccine exposure." Thus, the standard of Rule 23(b)(3) applies, and to maintain a class action, the court must find "that the questions of law or fact common to class members predominate over any questions affecting only individual members, and that a class action is superior to other available methods for fairly and efficiently adjudicating the controversy." Fed.R.Civ.P. 23(b)(3).

#### b. Medical Monitoring under Louisiana Law

\*6 In Bourgeois v. A.P. Green Indus., Inc., 716 So.2d 355, 360–61 (La.1998) (Bourgeois I ), the Supreme Court of Louisiana held that medical monitoring costs are compensable damages under Louisiana Civil Code article 2315 for an asymptomatic plaintiff who experienced significant exposure to a harmful substance and must incur the expense of periodic medical examinations to monitor the effects of that exposure, provided that the plaintiff demonstrates: (1) a significant exposure to a proven hazardous substance; (2) as a proximate result of this exposure, plaintiff suffers a significant risk of contracting a serious latent disease; (3) plaintiff's risk of contracting a serious latent disease is greater than (a) the risk of contracting the same disease had he not been exposed and (b) the chances of members of the public at large of developing this disease; (4) a monitoring procedure exists that makes the early detection of the disease possible; (5) the monitoring procedure has been prescribed by a qualified physician and is reasonably necessary according to contemporary scientific principles; (6) the prescribed monitoring regime is different from that typically recommended in the absence of exposure; and (7) there is some demonstrated clinical value in the early diagnosis and detection of the disease. In so holding, the Supreme Court of Louisiana explained the reasoning behind awarding damages for medical monitoring:

An action for medical monitoring seeks to recover the quantifiable costs of periodic medical examinations necessary to detect the onset of physical harm. The theory behind such recovery is simple. When a plaintiff is exposed to a hazardous substance, ..., it is often sound medical practice to undergo periodic examinations to ascertain whether the plaintiff has contracted a disease. This is because ... modern environmental toxins affect[] the body in ways that often do not become manifest for many years. Unlike a car crash, [toxic] exposure is an accident almost always without impact. Nevertheless, it is still an accident that can have consequences every bit as real as those sustained in a head-on collision. In fact, it is precisely because [toxins] can have such deadly consequences that plaintiffs, regardless of whether or not they are currently suffering from a disease, are often encouraged to submit to regular diagnostic testing.

Id. at 358–59 (internal citations omitted).

On July 9, 1999, Louisiana Civil Code article 2315 was amended to exclude future medical monitoring for asymptomatic plaintiffs. Louisiana Civil Code article 2315(B) states that "[d]amages do not include costs for future medical treatment, services, surveillance, or procedures of any kind unless such treatment, services, surveillance, or procedures are directly related to a manifest physical or mental injury or disease." See also Bonnette v. Conoco, Inc., 837 So.2d 1219, 1230 n. 6 (La.2003) (explaining that "the amendment effectively eliminated medical monitoring as a compensable item of damage in the absence of manifest physical or mental injury or disease").

\*7 Thereafter, in Bourgeois v. A.P. Green Indus., Inc., 783 So.2d 1251, 1260 (La.2001) (Bourgeois II) the Supreme Court of Louisiana held that the 1999 amendment to Article 2315(B) could not apply retroactively to divest a cause of action that accrued before the effective date of the amendment. Accordingly, to state a claim for damages for medical monitoring following the amendment to Article 2315(B) and Supreme Court of Louisiana's decision in Bourgeois II, a plaintiff must either: (1) have a manifest physical or mental injury or disease as required by Article 2315(B); or. (2) demonstrate that the seven factors forming the Bourgeois I test existed before July 9, 1999. See LA. CIV. CODE art. 2315(B); Crooks v. Metro. Life Ins. Co., 785 So.2d 810, 812 (La .2001); see also Burmaster v. Plaquemines Parish Gov't, 982 So.2d 795, 806 (La.2008).

Plaintiffs seek to certify a class of:

All children and infants who have received injections of vaccines containing Thimerosal and were exposed to multiple concomitant vaccines or intrauterine exposure through injections to the mother of injectable medications containing Thimerosal, who may develop mercuric neurotoxic disorders.

The complaint alleges that the class consists of "children suffering from mercurialism and later diagnosed generally with ASD, PDD and/or AS,<sup>6</sup>" and repeatedly refers to latent neurological injuries and diseases. In this case, plaintiffs allege that Jacob experienced harmful exposure prior to July 9, 1999, and that he sustained a manifest physical or mental injury. Therefore, both the *Bourgeois I* and the Article 2315(B) standards may be applicable.

ASD, PDD and AS refer to Autism Spectrum Disorder, Pervasive Developmental Disorder and Asperger's Syndrome, respectively.

#### i. Bourgeois I

To state a claim for medical monitoring under *Bourgeois I*, plaintiffs must allege that seven factors forming the *Bourgeois I* test existed before July 9, 1999. *See Crooks*, 785 So.2d at 812. Specifically, plaintiffs must allege a harmful exposure to a proven hazardous substance that resulted in a significant risk of contracting a serious latent disease, and that a physician prescribed a monitoring program that is reasonably necessary for early detection and different from that typically recommended in the absence of exposure. *See Bourgeois I*, 716 So.2d at 360–61.

Plaintiffs have not stated a claim for medical monitoring under *Bourgeois I*, because they do not allege that Jacob is at significant risk of contracting a latent disease, but rather that he has already manifested neurological injuries. Further, plaintiffs have not alleged that a physician has recommended a monitoring program for Jacob for early detection, rather than continuing care for his manifested issues. Jacob is not an appropriate class representative. Therefore, plaintiffs lack standing to bring a class action claim for medical monitoring under *Bourgeois I*.

#### **ii.** Article 2315(B)

To state a claim for medical monitoring under Article 2315(B), plaintiffs must allege a manifest physical or mental injury or disease that requires medical monitoring. Plaintiffs allege that Jacob has sustained a manifest neurological injury. However, they have not alleged that he requires medical monitoring to prevent a specific potential future disease, as opposed to future medical expenses to treat his manifested issues. There is no allegation that Jacob's condition is progressive or that he could develop a new condition due to exposure to Thimerosal-containing vaccines in 1998 that could be avoided or minimized by medical monitoring. Therefore, Jacob is not an appropriate class representative, and plaintiffs lack standing to bring a class action claim for medical monitoring under Article 2315(B). Thus, plaintiffs' claim for a medical monitoring class action is DISMISSED WITHOUT PREJUDICE for lack of subject matter jurisdiction.

#### 2. Injunction (Count II)

\*8 The vaccine defendants argue that plaintiffs do not have standing to pursue an injunction preventing them from selling Thimerosal-containing vaccines because plaintiffs do not allege that they are subjected to a real and immediate threat of being exposed to Thimerosal-containing vaccines in the future.

A plaintiff has standing to pursue an injunction when there is a "real and immediate threat of future injury" that is not merely conjectural. *K.P. v. LeBlanc*, 627 F.3d 115, 122–23 (5th Cir.2010) (quoting *City of L.A. v. Lyons*, 103 S.Ct. 1660, 1668 n .8 (1983)). Thus, "in order to have standing to seek injunctive relief, plaintiffs must demonstrate that they are likely to suffer future injury by the defendant." *Id.* at 123.

Plaintiffs allege that the vaccine defendants "placed into the marketplace and stream of commerce in Louisiana vaccines destined to be used in infants and children younger than seven years of age that contain Thimerosal as a preservative." They further allege that those vaccines have not been recalled, although Thimerosal-free vaccines are available, and seek an injunction preventing future use of the Thimerosal-containing vaccines. Plaintiffs allege that Jacob is "exposed to potential injection with the stockpiled vaccines containing mercury," but plaintiffs do not demonstrate that there is a real and immediate threat of the proposed future injury. Jacob, who was born in 1998, is more than seven years old. Therefore, he is not a "child younger than seven years of age" on whom the Thimerosal-containing vaccines are "destined to be used." Further, Jacob's parents are unlikely to permit Jacob to receive

any Thimerosal-containing vaccine, and he is unlikely to receive it without their consent. Jacob is not likely to suffer the complained of future injury. Thus, plaintiffs do not have standing to pursue the injunctive relief stated in the complaint, and that claim is DISMISSED WITHOUT PREJUDICE for lack of subject matter jurisdiction.

III. Defendants' Motions to Dismiss or for Judgment on the Pleadings as to Dale and Angel Guillot's Claims for Mental Anguish and Loss of Consortium in Count XI of the Complaint (Docs.# 49, 51, 55)

#### A. Legal Standard

"The standard for dismissal under Rule 12(c) is the same as that for dismissal for failure to state a claim under Rule 12(b)(6)." Chauvin v. State Farm & Cas. Co., 495 F.3d 232, 237 (5th Cir.2007). To survive a Rule 12(b)(6) motion to dismiss, enough facts to state a claim for relief that is plausible on its face must be pleaded. In re Katrina Canal Breaches Litig., 495 F.3d 191, 205 (5th Cir.2007) (quoting Bell Atl. v. Twombly, 127 S.Ct. 1955, 1964-65 & 1973 n. 14 (2007)). A claim is plausible on its face when the plaintiff pleads facts from which the court can "draw the reasonable inference that the defendant is liable for the misconduct alleged." Ashcroft v. Iqbal, 129 S.Ct. 1937, 1949 (2009). "Factual allegations must be enough to raise a right to relief above the speculative level, on the assumption that all the allegations in the complaint are true (even if doubtful in fact)." Bell Atl., 127 S.Ct. at 1965. The court "must accept all well-pleaded facts as true and view them in the light most favorable to the non-moving party." In re S. Scrap Material Co., LLC, 541 F.3d 584, 587 (5th Cir.2008). However, the court need not accept legal conclusions couched as factual allegations as true. *Iqbal*, 129 S.Ct. at 1949–50.

\*9 In considering a motion to dismiss for failure to state a claim, a district court may consider only the contents of the pleading and the attachments thereto. *Collins v. Morgan Stanley Dean Witter*, 224 F.3d 496, 498 (5th Cir.2000) (citing Fed.R.Civ.P. 12(b)(6)). However, "[d]ocuments that a defendant attaches to a motion to dismiss are considered part of the pleadings if they are referred to in the plaintiff's complaint and are central to her claim." *Id.* at 498–99 (internal citations omitted).

### B. Dale and Angel Guillot's Mental Anguish Claims (Count XI)

Defendants argue that Dale and Angel Guillot cannot maintain bystander claims under Louisiana law for mental anguish due to Jacob's injuries.

Under Louisiana Civil Code article 2315.6(B), claims for mental anguish and emotional distress for injury caused to another person are limited to "persons who view an event causing injury to another person, or who come upon the scene of the event soon thereafter ..." Further, "the injured person must suffer such harm that one can reasonably expect a person in the claimant's position to suffer serious mental anguish or emotional distress from the experience, and the claimant's mental anguish or emotional distress must be severe, debilitating, and foreseeable." La. Civ.Code art. 2315.6(B).

In *Trahan v. McManus*, 728 So.2d 1273, 1279 (La.1999), the Supreme Court of Louisiana explained that:

bystander damages are intended to provide a remedy when severe mental distress arises directly and immediately from the claimant's observing a traumatic injury-causing event to the direct victim. In order to recover, the claimant who observes the injury-causing event (or soon thereafter comes upon the scene of the injury) must be contemporaneously aware that the event has caused harm to the direct victim. The requirement of temporal proximity has always been at the root of allowing recovery for emotional distress caused by an injury to another, whether recovery is limited to one who actually witnessed a traumatic injury, or whether recovery is extended to one coming upon the traumatic injury, as under the Louisiana rule. Recovery of damages for mental anguish has almost never been extended to one who observed the victim's suffering at a place other than where the injury-causing event occurred or at a time not closely connected to the event.

The requirements of Article 2315.6, when read together, suggest a need for temporal proximity between the tortious event, the victim's observable harm, and the plaintiff's mental distress arising from an awareness of the harm caused by the event. The Legislature apparently intended to allow recovery of bystander damages to compensate for the immediate shock of witnessing a traumatic event which caused the direct victim immediate harm that is severe and apparent, but not to compensate for the anguish and distress that normally accompany an injury to a loved one under all circumstances.

\*10 Dale and Angel Guillot allege that they suffered mental anguish as a result of Jacob's receiving Thimerosal-containing vaccines and later developing neurological issues. Their allegations demonstrate that they were not contemporaneously aware of harm to Jacob at the time he received the vaccines. Because they do not allege that they witnessed an event that immediately caused Jacob's injuries, Dale and Angel Guillot cannot maintain bystander claims for mental anguish under Louisiana law. Therefore, Dale and Angel Guillot's bystander claims for mental anguish are DISMISSED WITH PREJUDICE.

### C. Dale and Angel Guillot's Loss of Consortium Claims (Count XI)

Defendants argue that Dale and Angel Guillot's loss of consortium claims are prescribed, because those damage claims arise under the LPLA, which has a one-year prescriptive period.

Louisiana Civil Code article 2315 provides that tort "[d]amages may include loss of consortium, service, and society, and shall be recoverable by the same respective categories of persons who would have a cause of action for wrongful death of an injured person." Pursuant to Louisiana Civil Code article 2315.2(A)(2), the parents of a child who does not have a spouse or children of their own can recover such damages. Jacob Guillot did not have a spouse or children, therefore, his parents, Dale and Angel Guillot, have a claim for loss of consortium due to Jacob's injuries. See La. Civ.Code arts. 2315, 2315.2; see also Morrison v. Kappa Alpha Psi Fraternity, 738 So.2d 1105, 1122 (La.Ct.App.1999) ("Civil Code art 2315 gives parents a cause of action for loss of consortium when their child is injured by the fault of another").

Under Louisiana law, the LPLA, "establishes the exclusive theories of liability for manufacturers for damages caused by their products," and "[a] claimant may not recover from a manufacturer for damage caused by a product on the basis of any [other] theory of liability." La.Rev.Stat. § 9:2800.52. The LPLA defines "damage" as "all damage caused by a product, including survival and wrongful death damages, for which Civil Code Articles 2315, 2315 .1 and 2315.2 allow recovery." Thus, Dale and Angel Guillot's loss of consortium damage claims, which arise under Article 2315, are covered by the LPLA.

LPLA claims are subject to the general one-year prescriptive period applicable to delictual actions under Louisiana law. La. Civ.Code art. 3492. "The prescription commences to run from the day the injury or damage is sustained." *Id.* In *Harvey v. Dixie Graphics, Inc.*, 593 So.2d 351, 354 (La.1992), the Supreme Court of Louisiana explained that:

[Louisiana Civil Code article 3492] is rooted in the recognition that a prescriptive period is a time limitation on the exercise of a right of action, and a right of action in tort comes into being only when the plaintiff's right to be free of illegal damage has been violated. When damages are not immediate, the action in damages thus is formed and begins to prescribe only when the tortious act actually produces damage and not on the day that the act was committed.

\*11 The damage suffered must at least be actual and appreciable in quality—that is, determinable and not merely speculative. But there is no requirement that the quantum of damages be certain or that they be fully incurred, or incurred in some particular quantum, before the plaintiff has a right of action. Thus, in cases in which a plaintiff has suffered some but not all of his damages, prescription runs from the date on which he first suffered actual and appreciable damage, even though he may thereafter come to a more precise realization of the damages he has already incurred or incur further damage as a result of the completed tortious act.

(citations omitted). Therefore, damage is sustained "when it has manifested itself with sufficiency certainty to support accrual of a cause of action." *Bailey v. Khoury*, 891 So.2d 1268, 1283 (La.2005).

Under Louisiana law, a cause of action accrues when a party has the right to sue, which requires fault, causation, and damages. *Ebinger v. Venus Constr. Corp.*, 65 So.3d 1279, 1286 (La.2011) (citing *Bourgeois II*, 783 So.2d at 1259; *Owens v. Martin*, 449 So.2d 448, 451 (La.1984)). "Further, liberative prescription of one year generally begins to run when the victim knows or should know of the damage, the delict and the relationship between them." *Bailey*, 891 So.2d at 1283 (citing *Branch v. Willis–Kinghton Med. Ctr.*, 636 So.2d 211, 212 (La.1994)). Thus, "prescription commences when a plaintiff obtains actual or constructive knowledge of facts indicating to a reasonable person that he or she is the victim of a tort." *Id.* (quoting *Campo v. Correa*, 828 So.2d 502, 508 (La.2002)).

Generally, the party asserting prescription has the burden of proof. *Eastin v. Entergy Corp.*, 865 So.2d 49, 54 (La.2004). "However, if prescription is evident on the face of the pleadings, ..., the burden shifts to the plaintiff to show that

the action has not prescribed." *Id.* In other words, the plaintiff must establish a suspension or interruption of the prescriptive period. *Bartucci v. Jackson*, 245 Fed. App'x 254, 257 (5th Cir.2007).

In this case, plaintiffs allege that Jacob was born on February 16, 1998, and sustained noticeable neurological injury at approximately eighteen months of age due to "the accumulation of Mercury in his body" from vaccinations. Plaintiffs allege that prior to eighteen months of age, Jacob "achieved every developmental milestone anticipated of all normally developing children," but thereafter, he "suddenly regressed developmentally, losing milestones of neurological development previously achieved," "becoming withdrawn, unable to speak, unresponsive to his environment, [and] engaging in repetitive behavior." Further, Jacob's medical records state that he developed encephalopathy the day he received a diphtheria, tetanus and pertussis vaccination in May 1999. After the injection he refused to eat or drink, became less involved, lost eye contact and refused to be held or rocked. He also stopped responding to his name, did not acknowledge his siblings and started banging his head on the floor and walls and screaming constantly. The allegations in plaintiffs' complaint establish that Dale and Angel Guillot knew or should have known of the alleged damage caused by the vaccines in 1999. They did not file their complaint until 2002, more than one year after they knew or should have known of the alleged damage. Thus, their claims for loss of consortium under the LPLA are prescribed, and those claims are DISMISSED WITH PREJUDICE.

Article 3492 provides that prescription "does not run against minors or interdicts in actions involving permanent disability and brought pursuant to the Louisiana Products Liability Act or state law governing product liability actions in effect at the time of the injury or damage." La. Civ.Code art. 3492. Thus, prescription has not run against Jacob's LPLA claims. However, it has run against Dale and Angel Guillots' personal claims related to Jacob's alleged injuries.

## IV. Plaintiffs' Motion for Leave to File an Amended Complaint (Doc. #81)

\*12 Plaintiffs seek leave of court to supplement and amend the complaint. Plaintiffs reiterate verbatim their claims for a medical monitoring class action, injunction, and for Dale and Angel Guillot's loss of consortium and mental anguish (Proposed Amended Complaint Counts I, II and VIII). All of these claims are discussed above.<sup>8</sup>

Additionally, plaintiffs seek to bring claims under the LPLA (Proposed Amended Complaint Count III), redhibition (Proposed Amended Complaint Count IV), breach of the vaccine defendant's warranty of fitness for a specific purpose (Proposed Amended Complaint Count V), breach of express/implied warranty (Proposed Amended Complaint Count VI), and LUTPA (Proposed Amended Complaint Count VII).

As stated above, plaintiffs cannot prevail on these claims.

Because the allegations in the Proposed Amended Complaint regarding these claims are identical to those in the original complaint, the court will not further discuss them, and plaintiffs' motion to amend the complaint is DENIED as to Counts I and II and Count VIII, as to Dale and Angel Guillot's loss or consortium and mental anguish claims, of the Proposed Amended Complaint.

#### A. Legal Standard

Rule 15(a)(2) of the Federal Rules of Civil Procedure provides that "a party may amend its pleading only with the opposing party's consent or the court's leave. The court should freely give leave when justice so requires." The court has discretion on whether to grant or deny leave to amend. Addington v. Farmer's Elevator Mut. Ins. Co., 650 F.2d 663, 666 (5th Cir.1981). A court may deny leave to amend due to "undue delay, bad faith or dilatory motive on the part of the movant, repeated failure to cure deficiencies by amendments previously allowed, undue prejudice to the opposing party by virtue of allowance of the amendment, [and] futility of amendment ." Wright v. Allstate Ins. Co., 415 F.3d 384 (5th Cir.2005) (quoting Foman v. Davis, 83 S.Ct. 227, 230 (1962)). "Clearly, if the complaint as amended would still be subject to dismissal" leave to amend should be denied. Addington, 650 F.2d at 667.

# B. Plaintiffs' Proposed Claims Against the Vaccine Defendants (Proposed Amended Complaint Counts III through VIII)

In 1986, Congress enacted the Vaccine Act "to achieve optimal prevention of human infectious disease through immunization and to achieve optimal prevention against adverse reactions to vaccines." 42 U.S.C. § 300aa–1. "The Vaccine Act is a remedial program designed to provide swift compensation for persons injured by vaccines, while ensuring that the nation's supply of vaccines isn't unduly threatened by the costs and risks of tort litigation." *Moss v. Merck & Co.*, 381 F.3d 501, 503 (5th Cir.2004). It was enacted "ostensibly as a federal mechanism beyond the traditional tort law paradigm to provide a trust fund for claimants asserting

that they had been harmed through the use of childhood vaccines." *McDonal v. Abbot Laboratories*, 408 F.3d 177, 184 (5th Cir.2005) (citing *Schafer v. Am. Cyanamid Co.*, 20 F.3d 1, 2 (1st Cir.1994)).

The Vaccine Act requires a person who has sustained a vaccine-related injury or death, 9 or that person's legal representative, to file a petition against the United States Government in the United States Court of Federal Claims, whereupon it is assigned to a special master for adjudication. 42 U.S.C. §§ 300aa–11, 300aa–12. The petition must be filed within "36 months afer the date of the occurrence of the first symptom or manifestation of onset or of the significant aggravation of such injury." *Id.* at § 300aa–16(2). The claim must be fully adjudicated in the Vaccine Court prior to the claimant's bringing a civil action in State or Federal court. *Id.* at § 300aa–11. Section 300aa11(a)(2)(A) provides:

- "Vaccine-related injury or death" is defined as "an illness, injury, condition, or death associated with one or more of the vaccines set forth in the Vaccine Injury Table, except the term does not include illness, injury, condition, or death associated with an adulterant or contaminant intentionally added to such vaccine." 42 U.S.C. § 300aa—33(5).
  - \*13 No person may bring a civil action for damages in an amount greater than \$1,000 or in an unspecified amount against a vaccine administrator or manufacturer <sup>10</sup> in State or Federal court for damages arising from a vaccine-related injury or death associated with the administration of a vaccine after October 1, 1988, and no such court may award damages in an amount greater than \$1,000 in a civil action for damages for such vaccine-related injury or death, unless a petition has been filed, in accordance with section 300aa—16 of this title, for compensation under the Program for such injury or death and—
- The United States Court of Appeals for the Fifth Circuit has held that Thimerosal, "when used as a preservative is a component of a vaccine rather than an adulterant," but that Thimerosal manufactures are not vaccine manufacturers under the Vaccine Act. Moss, 381 F.3d at 503–4; see also McDonal, 408 F.3d at 185; see also Holder v. Abbot Laboratories, Inc., 444 F.3d 383, 389 (5th Cir.2006). Thus, "[t]here is no requirement that redress for vaccine-related injuries against Thimerosal manufacturers be pursued in accordance with section 300aa–11(a)" Holder, 444 F.3d at 389. As a result, plaintiffs were not required to pursue their claims against

the Thimerosal defendants in the Vaccine Court prior to bringing civil tort claims against them in federal court.

- (i)(I) the United States Court of Federal Claims has issued a judgment under section 300aa–12 of this title on such petition, and
  - (II) such person elects under section 300aa–21(a) of this title to file such an action, or
  - (ii) such person elects to withdraw such petition under section 300aa21(b) of this title or such petition is considered withdrawn under such section.
- 42 U.S.C. § 300aa–11(a)(2)(A). A vaccine administrator or manufacturer cannot be made a party to any civil action, except one authorized by § 300aa–11(a)(1)(A), for damages for a vaccine-related injury or death associated with the administration of a vaccine after October 1, 1988. *Id.* at § 300aa–11(a)(3).

After the United States Court of Federal Claims enters judgment on the petition made under the Vaccine Act, the petitioner must file an election, in writing, with the clerk of that court in accordance with § 300aa–21(a). If the judgment awarded compensation, the petitioner must elect either to receive the compensation or file a civil action for damages. *Id.* Alternatively, if the judgment did not award compensation, the petitioner must elect to accept the judgment or file a civil action for damages. *Id.* The election must be filed "not later than 90 days after the date of the court's final judgment with respect to which the election is to be made." *Id.* If the election is not timely filed, the petitioner "shall be deemed to have filed an election to accept the judgment of the court." *Id.* 

In this case, the United States Court of Federal Claims entered a judgment on plaintiffs' Vaccine Court petition on April 11, 2012. Plaintiffs did not file an election to proceed with a civil action until more than ninety days later, on November 5, 2012. Although plaintiffs filed two Rule 60(b) motions, "the Court of Federal Claims cannot use Rule 60(b) to extend the time of the election under 42 U.S.C. § 300aa-21 (a)." Bailiss v. Sec'y of the Dep't of Health and Human Servs., 37 Fed. Cl. 64, 67 (Fed.Cl.1996). "Just as Federal Rule of Civil Procedure 60(b) cannot be employed to toll, extend, or waive the time period for appeal, so the Court of Federal Claims analog cannot be used to extend the time within which an election must be filed under § 21(a) of the Vaccine Act," because the Vaccine Act does not give the court any "authority to waive the time limits Congress provided for filing an election." Gilbert v. Sec'y of Health and Human Servs., 51 F.3d 254, 257 (Fed.Cir.1995) (quotations and citations omitted). Therefore,

under § 300aa–21(a), plaintiffs are deemed to have filed an election to accept the judgment dismissing their Vaccine Court petition, and may not proceed with a civil action against the vaccine defendants, because they cannot fulfill the requirements of § 300aa–11(a)(1)(A) for bringing a civil action against the vaccine defendants. As a result, plaintiffs' motion to amend the complaint to bring Counts III through VIII against the vaccine defendants is DENIED because to allow such amendment would be futile.

### C. Plaintiffs' Claims against the Thimerosal Defendants (Proposed Amended Complaint Counts III, IV, VI, VII & VIII)

\*14 Plaintiffs seek to assert claims under the LPLA, LUTPA, redhibition, and breach of express and implied warranties against the Thimerosal defendants.

### 1. Louisiana Products Liability Act (Proposed Amended Complaint Count III)

#### a. Exclusivity of the LPLA

The LPLA, "establishes the exclusive theories of liability for manufacturers for damages 11 caused by their products," and "[a] claimant may not recover from a manufacturer for damage caused by a product on the basis of any [other] theory of liability." La.Rev.Stat. § 9:2800.52. While the methods of establishing an entitlement to recovery under the LPLA "are predicated on principles of strict liability, negligence, or warranty, respectively, neither negligence, strict liability, nor breach of express warranty is any longer available as an independent theory of recovery against a manufacturer." *Jefferson v. Lead Indus. Ass'n, Inc.*, 106 F.3d 1245, 1251 (5th Cir.1997). Moreover, "breach of implied warranty or redhibition is not available as a theory of recovery for personal injury, although a redhibition action is still viable against the manufacturer to recover pecuniary loss." *Id*.

The LPLA defines "damage" as "all damage caused by a product, including survival and wrongful death damages, for which Civil Code Articles 2315, 2315.1 and 2315.2 allow recovery." Thus, Dale and Angel Guillot's claims for economic damages for medical and related expenses incurred on Jacob's behalf and for Jacob's lost earnings or earning ability under Article 2315 included in Count VIII of the Proposed Amended Complaint are covered by the LPLA.

Because the LPLA is the exclusive remedy for damages caused by a manufacturer's product, except for redhibition for

pecuniary loss, plaintiffs cannot assert claims under LUTPA <sup>12</sup> or separate breach of express or implied warranty claims against the Thimerosal defendants. Thus, plaintiffs' motion to amend the complaint is DENIED as to asserting Counts VI and VII of the Proposed Amended Complaint against the Thimerosal defendants.

LUTPA has a one-year peremptive period that runs from the time of the transaction or act that gave rise to the action, and is not subject to suspension, interruption or the doctrine of contra non valentum. *Tubos de Acero de Mex., S.A. v. Am. Intern. Inv. Corp., Inc.,* 292 F.3d 471, 481 n. 4 (2002). The transaction that gave rise to plaintiffs' action was the vaccination that caused Jacob's encephelopathy in 1999. Therefore, if plaintiffs could assert a claim under LUTPA, it would be perempted.

#### b. Elements of a Claim under the LPLA

A plaintiff must prove the following elements in a products liability cause of action under the LPLA: (1) that the defendant is a manufacturer of the product <sup>13</sup>; (2) that the claimant's damage was proximately caused by a characteristic of the product; (3) that the characteristic made the product unreasonably dangerous in one of the four ways provided in the statute; and (4) that the claimant's damage arose from a reasonably anticipated use of the product by the claimant or someone else. *Jefferson*, 106 F.3d at 1251(citing generally J. Kennedy, *A Primer on the Louisiana Products Liability Act*, 49 La. L.Rev. 565 (1989)); LA. REV. STAT. § 9:2800.54. A plaintiff may prove that a product was "unreasonably dangerous" only under one of four theories:

- The LPLA defines "product" as "a corporeal movable that is manufactured for placement into trade or commerce, including a product that forms a component part of or that is subsequently incorporated into another product or an immovable." La.Rev.Stat. § 9:2800.53(4). When a plaintiff brings suit against a manufacturer of a chemical that does not, in and of itself, qualify for protection under the Vaccine Act, such as Thimerosal, the plaintiff must prove that the injury was proximately caused by that singular component, rather than the vaccine itself as a whole. *Moss*, 381 F.3d at 504.
  - (1) The product is unreasonably dangerous in construction or composition as provided in R.S. 9:2800.55;
    - (2) The product is unreasonably dangerous in design as provided in R.S. 9:2800.56;

- (3) The product is unreasonably dangerous because of inadequate warning as provided in R.S. 9:2800.57; or
- (4) The product is unreasonably dangerous because it does not conform to an express warranty of the manufacturer about the product as provided in R.S. 9:2800.58.

*Jefferson*, 106 F.3d at 1251 (citing La.Rev.Stat. § 9:2800.54(B)(1–4)).

\*15 Rule 8(a)(2) of the Federal Rules of Civil Procedure states that pleadings must contain a short and plain statement of the claim showing that the pleader is entitled to relief. To comply with Rule 8(a)(2) a plaintiff does not need to plead specific facts, but only "give the defendant fair notice of what the ... claim is and the grounds upon which it rests.' "Twombly, 127 S.Ct. at 1964-65 (quoting Conley v. Gibson, 78 S.Ct. 99, 103 (1957)). However, "it demands more than an unadorned the-defendant-unlawfullyharmed-me accusation." Igbal, 129 S.Ct. at 1949. A pleading must have more than "labels and conclusions" or "a formulaic recitation of the elements of a cause of action." Id. A complaint will not "suffice if it tenders naked assertions devoid of further factual enhancement." Id. "Factual allegations must be enough to raise a right to relief above the speculative level." Twombly, 127 S.Ct. at 1965.

In the Proposed Amended Complaint, plaintiffs seek to bring LPLA claims against the Thimerosal defendants, alleging that they "are liable to the claimants for damage proximately caused by the toxic nature and character of the Thimerosal-containing vaccines that render the vaccines unreasonably dangerous when such damage arose from the reasonably anticipated use of the vaccines." Plaintiffs then make allegations directed to the LPLA theories under which a product can be unreasonably dangerous.

#### i. Construction or Composition

To prevail on a claim that a product is "unreasonably dangerous" in its "construction or composition" under the LPLA, a plaintiff must show that, "at the time the product left its manufacturer's control, the product deviated in a material way from the manufacturer's specifications or performance standards for the product or from otherwise identical products manufactured by the same manufacturer." La.Rev.Stat. § 9:2800.585; see also Stahl v. Novartis Pharm. Corp., 283 F.3d 254, 261 (5th Cir.2002). The "construction or composition" provision of the LPLA "provides a remedy for damages

caused by a product that is defective due to a mistake in the manufacturing process." *Stahl*, 283 F.3d at 263.

Plaintiffs' allegation in the Proposed Amended Complaint directed at a construction or composition claim under the LPLA is:

132. The *vaccines* at issue are unreasonably dangerous in construction or composition as provided in R.S. 9:2800.55 because the *vaccines* deviated in a material way from the manufacturers' specifications or performance standards for the product. Specifically, the FDA mandated that the preservatives used in the vaccines be safe and nontoxic. These *vaccines* deviated from identical products manufactured by the same manufacturer following removal of Thimerosal from the vaccines. At all times material thereto, the *vaccine manufacturers* could have made single dose vials without the use of Thimerosal, or the mercury-based compound.

\*16 (emphasis added).

This allegation is insufficient to state a construction or composition claim under the LPLA against the Thimerosal defendants, because it does not allege that the Thimerosal itself used in the vaccines Jacob received deviated in any material way from the Thimerosal manufacturers' "specifications or performance standards for" Thimerosal, or that there was a mistake in the Thimerosal manufacturing process. Indeed, this allegation is directed at the vaccine defendants, and alleges a design defect claim, by suggesting that the vaccines could have been made in single dose vials without using Thimerosal. Because plaintiffs have not adequately stated a construction or composition claim under the LPLA against the Thimerosal defendants, plaintiffs' motion to amend the complaint is DENIED as to asserting claims under the LPLA for construction or composition against the Thimerosal defendants.

#### ii. Design

A plaintiff asserting a design defect claim under the LPLA must show that: (1) an alternative design existed; and (2) "[t]he likelihood that the product's design would cause the claimant's damage and the gravity of that damage outweighed the burden on the manufacturer of adopting such alternative design and the adverse effect ... of such alternative design on the utility of the product." La.Rev.Stat. § 9:2800.56.

Plaintiffs' allegation in the Proposed Amended Complaint directed at a design defect claim under the LPLA is:

133. The vaccines at issue and the Thimerosal preservative at issue [are] unreasonably dangerous in design as provided in R.S. 9:2800.56 because, at the time the vaccines left its manufacturer's control: (1) there existed an alternative design for the products that was capable of preventing the plaintiffs' damages, namely single dose vials without [T]himerosal; and (2) the likelihood that the products' designs would cause the plaintiffs' damages and the gravity of that damage outweighed the burden on the manufacturer of adopting such alternative design and the adverse effect, if any, of such alternative design on the utility of the vaccines. The likelihood of damage is great when the manufacturers did not adequately warn prescribing physicians and consumers of the mercury toxicity of the vaccines, or the cumulative effect of multiple injections of the mercury-containing vaccines. This is so when there had been no safety testing of the effects of multiple and cumulative dosages of the mercury-based vaccines in adults and children, including pregnant women and infants, with developing organs and brains. The concomitant and aggregated injections of vaccines manufactured by the VACCINE MANUFACTURERS exposed him to mercury in excess of all known Federal safe limits. JACOB's total exposure to date exceeds 175 mcg of mercury, this exposure was the cause of his injuries, and single dose vials without Thimerosal would have prevented the injuries.

(emphasis added).

\*17 This allegation is insufficient to state a design defect claim under the LPLAh against the Thimerosal defendants, because it does not allege that an alterative design for Thimerosal existed that would not have affected the utility of the product. Indeed, this allegation is directed at the vaccine defendants in that it alleges an alternative design for the vaccines, i.e single dose vials without Thimerosal. Because plaintiffs have not adequately stated a design defect claim under the LPLA against the Thimerosal defendants, plaintiffs' motion to amend the complaint is DENIED as to asserting a design defect claim.

#### iii. Warning

La.Rev.Stat. § 9:2800.57(A) provides that a "product is unreasonably dangerous because an adequate warning about the product has not been provided if, at the time the product left its manufacturer's control, the product possessed a characteristic that may cause damage and the manufacturer failed to use reasonable care to provide an adequate warning of such characteristic and its danger to users and handlers of

the product." However, there is no duty to warn if "[t]he user or handler of the product already knows or reasonably should be expected to know of the characteristic of the product that may cause damage and the danger of such characteristic." Id. at § 9:2800.57(B)(2). Louisiana courts have held under the "sophisticated user" exception provided in § 9:2800.57(B) (2), and the prior law upon which that section is based, that manufacturers have no duty to warn an end-user of a product's dangers when the product is initially purchased by a sophisticated user that would have the duty to warn the enduser. See Longo v. E.I. Dupont De Nemours & Co., 632 So.2d 1193 (La.Ct.App.1994); Scallan v. Duriron Co., Inc., 11 F.3d 1249 (5th Cir.1994); Washington v. Dep't of Transp., 8 F.3d 296 (5th Cir.1993); Davis v. Avondale Indus., Inc., 975 F.2d 169 (5th Cir.1992); Bates v. E.D. Bullard Co., 76 So.3d 111 (La.Ct.App.2011).

Plaintiffs allegations in the Proposed Amended Complaint directed at a failure to warn claim under the LPLA are:

- 135. The Thimerosal-containing vaccines are unreasonably dangerous because an adequate warning about the products has not been provided as provided in R.S. 9:2800.57.
- 136. The Thimerosal-containing vaccines are unreasonably dangerous because an adequate warning about the vaccines has not been provided when, at the time the vaccines left the manufacturers' control, the vaccines possessed the unnecessary toxic characteristics that may cause damage and the manufacturers failed to use reasonable care to provide an adequate warning of such mercury toxicity and its danger to users, including infants, and prescribing physicians.
- 137. The Vaccine Manufacturers and the Thimerosal Manufacturers failed to warn or to adequately warn the prescribing physicians, and the manufacturers' failure to warn or adequately warn was the cause in fact and proximate cause of the plaintiff's injury.
- \*18 138. If the Vaccine Manufacturers and the Thimerosal Manufacturers had rendered adequate warnings concerning Thimerosal-containing vaccines, prescribers such as Plaintiff's prescriber would not have prescribed Thimerosal-containing vaccines to infants and children, such as the Plaintiff, and would have switched from Thimerosal-containing vaccines to safer vaccines, or would have refrained wholly from any use of Thimerosal-containing vaccines.

141. An adequate warning regarding the mercury toxicity of the vaccines and its cumulative effects in patients and its potential for causing neurological and cognitive damage in patients receiving multiple doses of Thimerosal in excess of EPA "safe levels" would have deterred Jacob's physicians from prescribing multiple and cumulative doses of Thimerosal-containing vaccines to plaintiff.

These allegations are sufficient to state a failure to warn claim under the LPLA against the Thimerosal defendants. The allegations state that the "Thimerosal-containing vaccines" were unreasonably dangerous and that the defendants failed to warn of the dangers of the "Thimerosal-containing vaccines." Clearly, the intent of the allegations is to state that the Thimerosal in the vaccines caused the alleged harm. Further, because there has been no discovery, there is no evidence in the record upon which the court can base a finding that the vaccine manufacturers were "sophisticated users" of Thimerosal who already knew or reasonably should be expected to have known of any characteristics of Thimerosal that may cause damage and the danger of such characteristics. Therefore, plaintiffs have adequately stated a failure to warn claim under the LPLA against the Thimerosal defendants, and plaintiffs' motion to amend the complaint is GRANTED as to asserting claims for failure of the Thimerosal defendants to provide adequate warning.

#### iv. Express Warranty

The LPLA provides:

A product is unreasonably dangerous when it does not conform to an express warranty made at any time by the manufacturer about the product if the express warranty has induced the claimant or another person or entity to use the product and the claimant's damage was proximately caused because the express warranty was untrue.

La.Rev.Stat. § 9:2800.5. The LPLA defines an "express warranty" as:

a representation, statement of alleged fact or promise about a product or its nature, material or workmanship that represents, affirms or promises that the product or its nature, material or workmanship possesses specified characteristics or qualities that will meet a specified level of performance.

La.Rev.Stat. § 9:2800.53(6).

Plaintiffs allegations in the Proposed Amended Complaint directed at an express warranty claim under the LPLA are:

- 145. The Thimerosal-containing vaccines are unreasonably dangerous because they do not conform to an express warranty of the manufacturers about the vaccines as provided in R.S. 9:2800.58.
- \*19 146. This is particular[ly] so where the Vaccine Manufacturers represented to the FDA that the preservatives used in the vaccine were "safe."
- 147. This representation is, under information and belief, made in each Vaccine Manufacturer's license application.
- 148. The express warranty put forth in the marketing, distribution, and sale efforts of the Vaccine Manufacturers, Thimerosal Manufacturers, and Distributer Defendants, and their sales teams and representatives, that the vaccines contain a "safe" preservative induced the plaintiffs and the prescribing physician to use the vaccines, and the Plaintiffs' damages were proximately caused because the express warranty was untrue.

These allegations are insufficient to state a breach of express warranty claim under the LPLA against the Thimerosal defendants. Plaintiffs do not allege the existence or content of any specific express warranty about Thimerosal with which the product did not conform. Plaintiffs do not allege any representation or statement of alleged fact or promise made by the Thimerosal defendants about Thimerosal or its nature, material or workmanship that represents, affirms or promises that Thimerosal or its nature, material or workmanship possessed specified characteristics or qualities that met a specified level of performance. Because plaintiffs have not adequately stated a breach of express warranty claim under the LPLA against the Thimerosal defendants, plaintiffs' motion to amend the complaint is DENIED as to asserting such claims.

## 2. Redhibition (Proposed Amended Complaint Count IV)

Redhibition is a viable claim against a manufacturer to recover pecuniary loss, but not as a theory of recovery for personal injury. *Jefferson*, 106 F.3d at 1251. "Redhibition is the avoidance of a sale because of some vice or defect in the thing sold. It requires the seller to return the purchase price and the buyer to return the thing purchased." *Capitol City Leasing Corp. v. Hill*, 404 So.2d 935, 939 (La.1981); *see also* La. Civ.Code arts. 2520, 2532. A defect is redhibitory, and

gives the buyer the right to obtain recision of the sale, "when it renders the thing useless, or its use so inconvenient that it must be presumed that a buyer would not have bought the thing had he known of the defect." La. Civ.Code art. 2520. A defect may also be redhibitory, and gives the buyer the right to a reduction in the price, "when, without rendering the thing totally useless, it diminishes its usefulness or its value so that it must be presumed that a buyer would still have bought it but for a lesser price." *Id.* 

In the Proposed Amended Complaint, plaintiffs recite Article 2520, and state that they "are entitled to recover their economic losses where there are redhibitory defects, or vices in the vaccines sold." Plaintiffs do not allege that they are seeking a return of the purchase prices or a reduction in the purchase prices of the vaccines. Instead, the allegations in the proposed amended complaint indicate that they are attempting to collect personal injury damages through a redhibition claim, which is prohibited under the LPLA. *Jefferson*, 106 F.3d at 1251. Thus, plaintiffs' motion to amend the complaint is DENIED as to asserting Count IV of the Proposed Amended Complaint because it would be futile.

#### CONCLUSION

\*20 IT IS HEREBY ORDERED that Eli Lilly and Company's Motion for Judgment on the Pleadings (Doc. #49) is **GRANTED.** 

**IT IS FURTHER ORDERED** that Sanofi Pasteur Inc., Merck Sharpe & Dohme Corp. and GlasxoSmithKlien LLC's Motion to Dismiss (Doc. # 51) is **GRANTED.** 

**IT IS FURTHER ORDERED** that American International Chemical, Inc.'s Motion to Dismiss (Doc. # 55) is **GRANTED.** 

**IT IS FURTHER ORDERED** that Plaintiffs' Motion to Strike (Doc. # 60) is **DENIED**.

IT IS FURTHER ORDERED that Plaintiffs' Motion for Leave to Supplement and Amend the Complaint (Doc. #81) is **GRANTED** as to bringing claims of Jacob Guillot under the Louisiana Products Liability Act ("LPLA"), Louisiana Revised Statutes § 9:2800.51, et seq., for failure to warn against Eli Lilly and Company, American International Chemical, and Spectrum Laboratory Products, Inc. (Count III of the Proposed Amended Complaint). The motion is DENIED as to asserting claims of Jacob under the LPLA for composition and construction, design defects and breach of warranty as to Eli Lilly and Company, American International Chemical, and Spectrum Laboratory Products, Inc. (Count III of the Proposed Amended Complaint), all proposed claims against Sanofi Pasteur Inc., Merck Sharpe & Dohme Corp. and GlasxoSmithKlien LLC's (Counts I through VIII of the Proposed Amended Complaint), and Counts I, II, and IV through VIII of the Proposed Amended Complaint against Eli Lilly and Company, American International Chemical, and Spectrum Laboratory Products, Inc.

#### **All Citations**

Not Reported in F.Supp.2d, 2013 WL 4508003

**End of Document** 

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# **Tab 12**

2006 WL 1371625 Only the Westlaw citation is currently available. United States District Court, D. Arizona.

Bob L. HANKS, Plaintiff,

Angela K. ANDREWS, et al., Defendant.

No. CV 05–2275–PHX–NVW. | May 15, 2006.

#### **Attorneys and Law Firms**

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#### **ORDER**

NEIL V. WAKE, District Judge.

\*1 The Court has before it Plaintiff's Second Amended Complaint. Doc. # 106.

Plaintiff ("Hanks") filed an initial Complaint against the defendants on August 1, 2005. On December 8, 2005, this Court dismissed Hanks's Complaint without prejudice for failure to comply with Rule 8 of the Federal Rules of Civil Procedure. Hanks filed his First Amended Complaint on December 30, 2005. On January 30, 2006, the Court reviewed Hanks's First Amended Complaint to see if it complied with Rule 8's pleading requirements and whether it stated a claim. The Court dismissed all of Hanks's claims. The Court instructed Hanks that if he elected to amend his Complaint a second time, he needed to comply with Rule 8.

On March 21, 2006, Hanks filed his Second Amended Complaint. The Court screens Hanks's Second Amended

Complaint pursuant to 28 U.S.C. § 1915(e)(2) to determine whether he complies with Rule 8 and states a claim.

#### I. Analysis

#### A. Federal Rules of Civil Procedure

The original Complaint in this action was dismissed because it did not contain "a short and plain statement of the claim[s] showing that the pleader is entitled to relief" as required by Rule 8(a) of the Federal Rules of Civil Procedure. The Court, however, granted Hanks leave to amend. The Court provided Hanks an example of a pleading which satisfies the requirements of Rule 8 and gave Hanks explicit instructions to assist him in correcting the deficiencies in his original Complaint. See Doc. #71 ("In the amended complaint, Hanks must write out the rights he believes were violated, the name of the person who violated the right, exactly what the individual did or failed to do, how the action or inaction of that person is connected to the violation of Hanks's right, and what specific injury Hanks suffered because of the other person's conduct."). Hanks was warned that if he failed to comply with each of the Court's instructions, the action would be dismissed pursuant to Rule 41(b) of the Federal Rules of Civil Procedure.

Hanks's First Amended Complaint failed to comply with Rule 8(a) of the Federal Rules of Civil Procedure. The Court also evaluated all of Hanks's claims to determine whether any stated a claim or whether any could possibly state a claim if Hanks alleged certain facts. The court instructed Hanks that if he elected "to file an amended complaint, he must sufficiently allege which defendants are liable under each claim, and he must allege as to each defendant 'a short and plain statement of the claim showing that the pleader is entitled to relief" as to each such defendant." Doc. # 101. Hanks was provided with another opportunity to amend his Complaint.

Hanks has amended his Complaint a second time, but it still fails to comply with the Court's instructions or the requirements of Rule 8. Hanks fails to present a short and plain statement that allows the defendants to form a responsive pleading. Hanks now presents a fifty-four page complaint, naming twenty-seven defendants and alleging nine causes of action. The Second Amended Complaint is extremely verbose and meandering. It is a jumble of factual assertions and legal conclusions that do not allow the defendants to form a response. The Second Amended Complaint must leave the defendants wondering what each is being sued for and how it connects with elements of any

basis of liability. Specifically, at the start of each claim, Hanks lists all of the defendants without alleging how each defendant's involvement with the particular claim. *See* Doc. # 106 at ¶¶ 228, 246, 262, 285, 307, 324, 348, 387, and 414 (listing the exact same defendants who acted "in concert" to harm Hanks). It is impossible for a defendant to read Hanks's Second Amended Complaint and know how to form a responsive pleading.

\*2 Moreover, Hanks attempts to allege ten causes of action in his Second Amended Complaint, but each Count merely incorporates by reference the undifferentiated mass of prior allegations in the entire complaint. By thus intermingling essentially all substantive allegations, Hanks does not comply with Rule 10(b), Fed.R.Civ.P., which states, "Each claim founded upon a separate transaction or occurrence and each defense other than denials shall be stated in a separate count or defense whenever a separation facilitates the clear presentation of the matters set forth." The Defendants are left to guess about which of the 226 paragraphs of general allegations relate to each claim for relief.

None of the counts in this Second Amended Complaint presents an intelligible picture of the nature of this lawsuit. In sum, the Complaint is vague and confusing and there is no plain or concise statement of the causes of action. This pleading would not give adequate notice to the defendants of what they must defend against. Although pro se pleadings are to be liberally construed, *Haines v. Kerner*, 404 U.S. 519 (1972), conclusory and vague allegations will not support a cause of action. Moreover, the liberal construction rule does not eliminate the Rule 8(e) requirement that "[e]ach averment of a pleading shall be simple, concise, and direct." The Court has given Hanks notice of these requirements to no avail. The Second Amended Complaint and this action will therefore be dismissed pursuant to Rule 8 and Rule 41(b).

Although the inquiry could end here, the conclusion to dismiss Hanks's Complaint is further supported by the fact that it is patently obvious that Hanks fails to state a claim for eight of his ten causes of action.

#### B. 28 U.S.C. § 1915(e)(2)

Because Hanks is proceeding in forma pauperis, the court is required to screen his Complaint pursuant to 28 U.S.C. § 1915(e)(2), which provides that a court must dismiss a complaint or portion thereof if the plaintiff has raised claims that are legally "frivolous or malicious," that fail to state a claim upon which relief may be granted, or that seek monetary

relief from a defendant who is immune from such relief. 28 U.S.C. § 1915(e)(2). In its January 30, 2006 Order, Hanks's claims were analyzed count-by-count to determine whether any stated a claim, and Hanks was provided with the elements necessary for each claim. Despite the Court's clear instruction, eight of Hanks's claims fall far short of stating a claim.

The Court addresses each count seriatim to determine whether Hanks has stated a claim.

#### 1. Fraud

On January 31, 2006, Hanks's fraud claim was dismissed for failure to allege that he relied on a false statement or that he had a right to rely on the alleged false statement. Hanks was informed that Rule 9(b) of the Federal Rules of Civil Procedure requires that claims of fraud be pled with particularity. Hanks was also informed of the elements necessary to state a claim for fraud. See Doc. # 101 (citing See Staheli v. Kauffman, 122 Ariz. 380, 383 (Ariz.1979)).

\*3 In his Second Amended Complaint, Hanks again fails to state a claim for fraud. Hanks fails to allege specific false statements that were made by particular defendants. Rather, Hanks attempts to couch a defendant's defense to one of his allegations as a false statement. See Doc. # 106 at ¶ 146 ("Defendants Forshey and JoAnn Kennedy represent and claim they had Dr. Kennedy's permission to remove, transport, use and convert Plaintiff's property..."). See also Id. at ¶ 267 ("Defendants Forshey, Sampair, and Simpson's denial of the civil conversion of Plaintiff's property was false."). These allegations do not identify false statements. The remainder of Hanks's fraud claim only includes even more general allegations. See Id. at ¶ 268 ("Defendants Forshey, Sampair and Simpson[] sent letters to Plaintiff in the U.S. Mail, (mail fraud) with false statements concerning a material fact of the conversion of the conversion of Plaintiff's Property.").

Moreover, other than conclusorily asserting such to be the case, Hanks fails to allege that any of the alleged misrepresentations proximately caused an injury. *See Id.* at ¶ 277 ("As a direct and proximate result of Defendants' unlawful, intentional, malicious, extreme and outrageous conduct and civil fraud, Plaintiff has been harmed and has suffered direct, indirect, and vicarious injuries, damages and consequential damages.").

Hanks has therefore failed adequately to allege fraud. General allegations are insufficient to satisfy Rule 9's particularity requirements.

#### 2. Invasion of Privacy Claims

#### a. False Light

Hanks's false light invasion of privacy claim was dismissed because he failed to allege the elements necessary to establish such a claim. In its Order, the Court explicitly stated the elements necessary to state a claim for false light. However, despite the Court's instructions, in his Second Amended Complaint, Hanks fails to allege that any of the statements "published" were "false." Instead, Hanks appears to allege merely that he was embarrassed when some of his private information received public attention. Thus, Hanks fails to state a claim for a false light.

#### b. Intrusion upon Seclusion

Hanks attempts to allege that the defendants intruded upon his seclusion. However, Hanks only alleges conclusory paragraphs stating that he has alleged a claim for intrusion upon seclusion. Hanks does not allege any facts other than asserting that a conversion of his property has occurred. This is insufficient to state a claim for intrusion upon seclusion. Hanks was informed of the necessary elements and failed to allege sufficient facts.

#### 3. Intentional Infliction of Emotional Distress

On January 31, 2006, Hanks's intentional infliction of emotional distress claim was dismissed because Hanks failed to demonstrate either (1) that he actually suffered severe emotional distress or (2) that any of the alleged misconduct constituted "extreme" or "outrageous" behavior. See Doc. # 101 (citing Citizen Publ. Co. v. Miller, 2005 Ariz. LEXIS 69,\* \*7–8, 115 P.3d 107, 110 (Ariz .2005) and Lucchesi v. Frederic N. Stimmel, M.D., Ltd., 149 Ariz. 76, 78, 716 P.2d 1013, 1016 (Ariz.1986)). Despite clear instructions, Hanks only conclusorily alleges that he suffered severe emotional distress as a result of JoAnn Kennedy's alleged conversion of Hanks's documents. Moreover, Hanks does not allege facts demonstrating "extreme" or "outrageous" conduct under Arizona case law.

\*4 The January 31, 2006 Order provided the elements necessary to state a claim for intentional infliction of emotional distress, but Hanks did not allege facts establishing

those elements. Hanks was also informed that conclusory allegations are insufficient.

#### 4. Abuse of Process

On January 31, 2006, Hanks's abuse of process claim was dismissed because he did not allege which process was misused. In his Second Amended Complaint, Hanks alleges that twenty-six defendants abused judicial process for improper purposes. Assuming that there was some form of judicial process involved—which is not immediately clear from the Second Amended Complaint—Hanks entirely fails to allege facts demonstrating how any process was abused for an improper purpose or for an ulterior motive. While Hanks conclusorily asserts such to be the case, see Doc. # 106 at ¶ 357 ("Defendants had an ulterior motive or purpose exercising such perverted use of the system or abuse of process."); Id. at ¶ 358 ("Defendants wilfully misused legal process to accomplish an ulterior purpose for which the process was not designed or intended."), conclusory allegations are insufficient.

Hanks therefore fails to state claim for abuse of process. Hanks has been instructed twice before that conclusory allegations are insufficient.

#### 5. Section 1983 Claim

Hanks's sole federal cause of action is a 42 U.S.C. § 1983 claim. "To prove a case under section 1983, the plaintiff must demonstrate that (1) the action occurred under color of state law and (2) the action resulted in the deprivation of a constitutional right or federal statutory right." *Jones v. Williams*, 297 F.3d 930, 934 (9th Cir.2002) (quotations and citations omitted). On January 30, 2006, Hanks was informed that in order to state a section 1983 claim, Hanks needed to allege a deprivation of a constitutional or federal right. Hanks was further informed that conclusory allegations are insufficient.

However, despite the Court's instruction, Hanks does not cite a constitutional provision or federal statute which the defendants allegedly violated. Hanks's only reference to a federal right is in ¶ 373, in which Hanks alleges that "Defendants Forshey and JoAnn Kennedy's acts in concert resulted in the State actor Defendant's deprivation of Plaintiff's constitutional rights or federal statutory right as claimed above." There is no mention of the particular constitutional provision or federal statutory right which was allegedly violated. Elsewhere in his Complaint, Hanks

alleges that the defendants' conduct violated his rights under the Fourth Amendment, the Fifth Amendment, and the Fourteenth Amendment. However, Hanks does not allege facts explaining how any of the defendants violated these constitutional provisions.

Hanks fails to allege facts stating a Section 1983 claim. Hanks was explicitly informed what he had to allege in order to state a Section 1983 claim and he failed to do so. Just listing constitutional provisions does not adequately state a claim.

#### 6. Negligence

\*5 Hanks appears to be alleging that Maricopa County and Arpaio negligently trained their officers. However, again, Hanks does not allege any facts substantiating such an allegation. Hanks just reiterates his earlier arguments—that the defendants, all twenty-six of them, improperly took his property from his dentist's safe. This is insufficient to state a claim of negligence.

#### 7. Unjust Enrichment

On January 31, 2006, Hanks's unjust enrichment claim was dismissed because of his failure to allege (1) how the defendants were enriched by his dental records and (2) how there is no adequate remedy at law. Hanks still fails to allege why there is no adequate remedy at law. As to this element, Hanks alleges that "[b]ecause Defendants ... refuse[d] to cause the criminal arrest of the Defendants and their associates who acted in conspiracy to steal Plaintiff's property, Plaintiff has no remedy provide[d] at law for recovery of his property." Doc. # 106, at ¶ 420. The fact that the defendants were not criminally prosecuted is irrelevant to whether Hanks has a remedy at law. Hanks has therefore failed to state a claim for unjust enrichment.

#### IX. Dismissal with Prejudice

The only claims for which it is not patently clear that Hanks cannot state a claim are his conversion and conspiracy claims. However, as discussed above, those claims are presented in a manner which makes it impossible for a defendant to formulate a responsive pleading. Hanks has twice been informed by the Court that he needs to allege each defendant's participation in a particular claim. Yet Hanks has failed on both occasions to follow the Court's instruction regarding this requirement. Instead, Hanks provides conclusory allegations without identifying individual defendants' actions. There is little to support the conclusion that if Hanks were provided

with a third opportunity to amend his Complaint, he would do so in a manner so as to comply with the Federal Rules of Civil Procedure. The question, then, is whether the Second Amended Complaint and this action should be dismissed pursuant to Rule 8 and Rule 41(b). See also 28 U.S.C. § 1915(e)(2)(B).

Pursuant to Rule 41(b) of the Federal Rules of Civil Procedure, the Court can dismiss an action "[f]or failure of the plaintiff to prosecute or to comply with these rules or any order of the court." *See Fjelstad v. American Honda Motor Co.*, 762 F.2d 1334, 1337 (9th Cir.1985). Before dismissing a case, however, the court must weigh the following five factors: 1) the public's interest in expeditious resolution of litigation; 2) the court's need to manage its docket; 3) the risk of prejudice to the defendants; 4) the public policy favoring disposition of cases on their merits; and 5) the availability of less drastic sanctions. *Malone v. U.S. Postal Serv.*, 833 F.2d 128, 130 (9th Cir.1987), *cert. denied*, 488 U.S. 819 (1988); *Thompson v. Housing Auth.*, 782 F.2d 829, 831 (9th Cir.1986).

\*6 The public's interest in expeditious resolution of cases "always favors dismissal." *Yourish v. Cal. Amplifier*, 191 F.3d 983, 990 (9th Cir.1999). The Court's need to manage its docket also weighs in favor of dismissal. The Court has expended extensive time on this case to attend to matters that parties are supposed to comply with without intervention of the court, to no avail. *See Pagtalunan v. Galaza*, 291 F.3d 639, 642 (9th Cir.2002). This district has one of the highest caseloads per judge in the country, and the burden of this kind of persistent pleading violation is substantial. The prejudice to the defendants is obvious. Defendants are entitled to ascertain what they are charged with and the legal sufficiency of those charges. People may not be haled into federal court and forced into battles with shadows. Thus, the third factor also weighs in favor of dismissal.

The fourth factor—the policy favoring disposition on the merits—is attenuated here. The Second Amended Complaint, like its predecessors, has an air of abuse and harassment. Indeed, with each amended complaint Hanks adds new defendants. The list of defendants has grown to 27—nine more defendants than named in Hanks's First Amended Complaint. The fact that Hanks disregards the proper procedures despite repeated guidance from the Court makes it look like the burdens the process imposes on others may be a principal end in itself.

The fourth factor—the availability of lesser sanctions—does not cut against dismissal. Hanks has been given three chances and two warnings in the clearest terms of what is required, yet he persists in his non-compliance with the Rules and with the Court's previous orders. This has been more than enough opportunity comply with the Rules if there were a good faith intention to comply. See McHenry v. Renne, 84 F.3d 1172, 1177 (9th Cir.1996) (affirming dismissal with prejudice of prolix, argumentative, and redundant amended complaint that did not comply with Rule 8(a)); Nevijel v. North Coast Life Ins. Co., 651 F.2d 671, 673-74 (9th Cir.1981)(affirming dismissal of amended complaint that was "equally as verbose, confusing, and conclusory as the initial complaint"); Corcoran v. Yorty, 347 F.2d 222, 223 (9th Cir.1965)(affirming dismissal without leave to amend second complaint that was "so verbose, confused and redundant that its true substance, if any, [was] well disguised").

Finally, parties, especially parties appearing before the court *pro se*, generally receive a specific warning about the possibility of dismissal before having the ultimate sanction imposed. *See*, *e.g.*, *Carey v. King*, 856 F.2d 1436, 1441 (9th Cir.1988); *Malone*, 833 F.2d at 133; *Hamilton v. Neptune* 

*Orient Lines, Ltd.*, 811 F.2d 498, 500 (9th Cir.1987). In this case, Hanks was warned in the Order entered December 8, 2005, Doc. #71, p. 5–6, that dismissal with prejudice would be the consequence of a further failure to comply with the Rules and with that Order.

\*7 The Court having weighed the appropriate considerations, the Second Amended Complaint and this action will be dismissed with prejudice pursuant to Rule 8 and Rule 41(b), Fed.R.Civ.P. See also 18 U.S.C. § 1915(e)(2)(B).

IT IS THEREFORE ORDERED that Plaintiff's Second Amended Complaint, Doc. # 106, is dismissed with prejudice. The Clerk shall note dismissal under 28 U.S.C. § 1915(e)(2) (B).

IT IS FURTHER ORDERED that the clerk shall enter judgment dismissing this action with prejudice. The clerk shall terminate this action.

#### **All Citations**

Not Reported in F.Supp.2d, 2006 WL 1371625

**End of Document** 

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## Tab 13

KeyCite Yellow Flag - Negative Treatment
Declined to Follow by Gress v. Freedom Mortgage Corporation, M.D.Pa.,
June 26, 2019

### 2019 WL 643709 **NOT FOR PUBLICATION**

United States District Court, D. New Jersey.

#### IN RE INSULIN PRICING LITIGATION

Civil Action No. 3:17-cv-0699-BRM-LHG | | Signed 02/15/2019

#### **OPINION**

#### BRIAN R. MARTINOTTI United States District Judge

\*1 Before this Court is a Motion to Dismiss filed by Defendant Novo Nordisk Inc. ("Novo") and Defendant Sanofi-Aventis U.S. LLC ("Sanofi") (collectively "Defendants") seeking to dismiss the putative plaintiffs' ("Plaintiffs") First Amended Complaint pursuant to Federal Rules of Civil Procedure 8(a), 9(b), and 12(b)(6). (ECF No. 158.) Plaintiffs filed an Opposition to Defendants' Motion to Dismiss. (ECF No. 181.) Defendants filed a Reply Brief to the Plaintiffs' Opposition. (ECF No. 190.) On January 17, 2019, this Court held oral argument on the limited issue of the applicability of the indirect purchaser rule to Plaintiffs' RICO claims, Counts One and Two. Plaintiffs' counsel supplemented the record by way of a letter brief to this Court on February 5, 2019. (ECF No. 249.) Defendants replied on February 8, 2019. (ECF No. 251.) For the reasons set forth herein, Defendants' Motion to Dismiss is GRANTED IN PART and DENIED IN PART.

Defendants' Motion to Dismiss is separated into two briefs. The first brief addresses Counts One (Violation of RICO), Two (Conspiracy to Violate RICO), Three (Violation of the New Jersey Consumer Fraud Act Against Novo), Four (Violation of the New Jersey Consumer Fraud Act Against Sanofi), and Five (Violation of the New Jersey Consumer Fraud Act Against Novo and Sanofi). (ECF No. 158-1.) The second brief focuses on Counts Six through Fifty-Nine, violations of the consumer fraud laws of the various states. (ECF No. 158-2.)

#### I. Background

#### A. Factual Background

The Plaintiffs are sixty-seven individuals, including one "Jane Doe," who filed the Complaint on behalf of themselves and a proposed nationwide class of analog insulin consumers. (Plaintiffs' First Amended Complaint (ECF No. 131) ¶¶ 21-155.) The Plaintiffs bring this action on behalf of themselves and all others similarly situated under Federal Rule of Civil Procedure 23(a) and 23(b)(3). (ECF No. 131 ¶ 280.) The Plaintiffs define their class as

"[a]ll individual persons in the United States and its territories who paid any portion of the purchase price for a prescription of Lantus, Levemir, Novolog, Apidra, and/or Toujeo at a price calculated by reference to a benchmark price, AWP (Average Wholesale Price),<sup>2</sup> or WAC (Wholesale Acquisition Price) for purposes other than resale."

(*Id*.)

The Plaintiffs frequently use the terms "benchmark price" and "sticker price" to refer to the AWP. (ECF No. 131 ¶¶ 1, 2, 174.)

Specifically, the class includes uninsured consumers, consumers in high-deductible health plans, consumers who reach the Medicare Part D donut hole, and consumers with high coinsurance rates. (*Id.* ¶ 282.) The Plaintiffs request this Court toll the class period to the "earliest date of the Defendant Drug Manufacturers' initiation of the scheme described herein." (*Id.* ¶ 283.)

Defendants are pharmaceutical companies headquartered in the United States. (*Id.* ¶¶ 157-58.) Defendants research, develop, and manufacture prescription medications. (*Id.*) Defendant Novo ("Novo") makes the "rapid-acting" analog insulin Novolog and the "long-acting" insulin Levemir. (*Id.* ¶ 282 (Table 2).) Novo introduced Novolog to the United States market in 2000 and Levemir in 2005. (*Id.*) Defendant Sanofi ("Sanofi") manufactures the "rapid-acting" insulin Apidra and the "long-acting" insulin Pantus. (*Id.*) Sanofi introduced Lantus to the United States market in 2000 and Apidra in 2004. Novo and Sanofi determine the sale price of their drugs, the AWP or WAC, and subsequently publish list prices for their analog insulins. (*Id.* ¶ 174.)

- \*2 The distribution of a branded prescription drug, such as the analog insulin at issue in this litigation, involves three transactions. First, a drug manufacturer sells its medication to a wholesaler. (*Id.* ¶¶ 163-164.) Second, the wholesaler takes possession of the medication and sells it to a pharmacy. (*Id.* ¶¶ 164, 170 fig. 3.) Third, the pharmacy sells the drug to the consumers. (*Id.* ¶¶ 164, 170 fig. 3.) Health insurers and pharmacy benefit managers ("PBMs"), which many insurers hire to manage their prescription drug benefits, are not directly involved in this distribution chain as they do not take physical possession of the medication. (*Id.* ¶¶ 165-66.)
- PBMs are retained by health insurance companies to manage their prescription drug benefits and negotiate, specifically for discounts, with drug companies and pharmacies on behalf of the health insurance companies. (ECF No. 131 ¶ 166.) PBMs do not purchase prescription drugs, nor do they make any payments to manufacturers. (*Id.*) PBMs typically do not take possession of drugs either, however, some PBMs operate mail-order pharmacies and purchase drugs from wholesalers solely in their capacity as a seller to the consumer. (ECF No. 131 ¶¶ 7, 166.)

Three separate payments are involved in the medication distribution chain: from the wholesaler to the manufacturer; from the pharmacy to the wholesaler; and from the consumer, and his or her insurer, if any, to the pharmacy. (Id. ¶ 168.) Additionally, there may also be a rebate payment from the manufacturer to the insurer or the insurer's PBM. (Id. ¶ 169.)

Wholesalers pay manufacturers based on the manufacturer's publicly reported list price, the WAC. (*Id.* ¶ 176.) The WAC is "the manufacturer's list price for the drug or biological to wholesalers or direct purchasers in the United States, not including prompt pay or other discounts, rebates, or reductions in price[.]" 42 U.S.C. § 1395w-3a(c)(6)(B). Accordingly, wholesalers pay the manufacturer the WAC price minus small percentage discounts derived via prompt payment or some other incentive. (ECF No. 131 ¶ 169, 176, 181.) Manufacturers are required to report the average price that wholesalers pay for each drug, accounting for any discounts, which is known as the Average Manufacturing Price ("AMP"). *See* 42 U.S.C. § 1396r-8(k)(1).

Wholesalers sell to pharmacies at a price negotiated with each individual pharmacy. (ECF No. 131  $\P$  176.) The prices paid by the pharmacies are frequently very close to the WAC, as wholesalers generally pay manufacturers the WAC minus a percentage discount. (*Id.*  $\P$  181.)

The consumer's purchase price is determined by his or her pharmacy, and in the case of insured consumers, by the terms of his or her insurance contract. (Id. ¶¶ 181, 183-184.) The drug manufacturers do not sell the drugs directly to the consumers, and as such, they do not set the price that the consumer pays for the prescription drug. (Id. ¶¶ 163, 171.) If a consumer is uninsured, the pharmacy independently determines the payment price. (Id. ¶¶ 182, 285.) If the consumer is insured, the insurance company or its PBM negotiates with the pharmacy to set a price. (Id. ¶¶ 166, 170 fig. 3, 171.) The insurer and the consumer each pay a portion of the negotiated price, subject to any deductibles or copayment requirements contained in the consumer's contract. (Id. ¶¶ 165, 183-184.) Plaintiffs contend that the prices charged by the pharmacies to uninsured consumers. and the prices set by insurers and PBMs for consumers subject to deductible and copayment requirements, are directly related to the AWP, or "benchmark" or "sticker" price. (Id. ¶¶ 2, 209.)

Plaintiffs allege that PBMs retain a portion of the rebate and pass the remainder of the cost on to the health insurance company and/or consumer. (*Id.* ¶¶ 4, 201, 204.) Plaintiffs further maintain that some insurers have elected not to pass on manufacturer rebates to consumers (*Id.* ¶ 200), and that as a result, the benchmark price is fraudulent because it does not account for manufacturer rebate payments made to PBMs. (*Id.* ¶¶ 252, 255). Additionally, Plaintiffs assert that spread between the "net price" and the benchmark price constitutes further evidence of a fraudulent scheme. (*Id.* ¶¶ 202, 206.)

- The "net price" refers to the revenue obtained by the manufacturer after subtracting the rebate amounts it negotiates and pays to PBMs. (ECF No. 131 ¶¶ 169, 170 fig. 3.) The net price may fluctuate as it necessarily depends on a particular PBM's negotiation. (ECF No. 131 ¶ 171.)
- \*3 Plaintiffs allege that PBM rebates are part of an industry scheme to inflate the price of analog insulin, whereby the three largest PBMs CVS Health, Express Scripts, and OptumRx use their leverage to create formularies, ranked lists of drugs. (*Id.* ¶¶ 169, 180.) Plaintiffs allege that health insurers "cover all or a portion of their members' drug costs based on whether and where drugs fall on their PBM formularies." (*Id.* ¶ 180.) If a drug is excluded from the formularies, consumers may be required to pay a larger share of the cost, or even the full cost. (*Id.* ¶¶ 193-94.) Plaintiffs assert that the use of formularies gives PBMs wide latitude to

extract rebates from manufacturers. (*Id.* ¶ 241.) Accordingly, Plaintiffs contend that Novo and Sanofi compete against one another by offering rebates to PBMs for formulary placements. (*Id.*)

Plaintiffs contend a pricing "scheme" to "widen a secret spread between the manufacturers' published and misleading benchmark prices, and their undisclosed, net selling prices for their analog insulins." (Id. ¶ 2.) Plaintiffs assert "PBM profits are tied to the size of the spread between the benchmark price and actual net selling prices," (Id. ¶¶ 2, 210) such that manufacturers have an incentive to offer a larger spread to PBMs than those offered by their competitors. (Id. ¶ 267). Plaintiffs premise their pricing scheme on two separate theories. First, Plaintiffs contend that Defendants "publicly report one price ... for their analog insulins while secretly offering a far lower price - the net price - to the largest PBMs." (Id. ¶ 2.) Plaintiffs argue that because PBMs do not "negotiate discounts or rebates" and instead merely "pad [their] pockets[,]" the rebates are illegitimate. (Id. ¶ 2, 6.) Second, Plaintiffs contend that Defendants misrepresented the benchmark prices as "reasonable approximations of the insulins' real prices." (Id. ¶¶ 3, 12-13, 254, 302, 350.) Plaintiffs allege that each of these schemes entails a "pattern" of predicate acts of federal mail and wire fraud in violation of 18 U.S.C. §§ 1341 and 1343, (Id. ¶ 326) and that these violations "have directly and proximately caused the plaintiffs and members of the class to be injured ... [through] inflated payments based on fictitious benchmark prices for the analog insulins." (*Id.* ¶¶ 20, 266, 336, 341, 354.)

#### **B. Procedural History**

On February 2, 2017, the first complaint was filed in this matter, Chaires, et. al v. Novo Nordisk, et al. ("In re Insulin"), Civil Action No. 17-699(BRM)(LHG). (ECF No. 1.) Thereafter, several prospective plaintiffs filed complaints in six separate actions: Barnett, et al. v. Novo Nordisk, Inc ("Barnett")., Civil Action No. 17-1580(BRM)(LHG); Boss, et al. v. CVS Health Corp. ("Boss"), Civil Action No. 17-1823(BRM)(LHG); Christensen, et al. v. Novo Nordisk, Inc., et al. ("Christensen"), Civil Action No. 17-2678(BRM)(LHG); Valdes, et al. v. Sanofi-Aventis U.S. LLC, et al. ("Valdes"), Civil Action No. 17-939(BRM)(LHG); Carfagno v. Novo Nordisk Inc. ("Carfagno"), Civil Action No. 17-3407(BRM)(LHG); and Bentele, et al. v. Eli Lilly & Co. ("Bentele"), Civil No. 18-11479(BRM)(LHG).

On February 22, 2017, this Court consolidated *Valdes* into *In re Insulin* absent objection from any parties, pursuant to Federal Rule of Civil Procedure 42(a). (ECF No. 11.) On September 18, 2017, this Court appointed Steve W. Berman, Esq. of Hagens Berman and James E. Cecchi, Esq. of Carella Byrne as interim lead Plaintiffs' counsel pursuant to Federal Rule of Civil Procedure 23(g). (ECF Nos. 71 & 72.) On January 3, 2018, this Court consolidated *Carfagno* into *In re Insulin* absent objection from any of the parties. (ECF No. 84.) On January 19, 2018, this Court consolidated *Barnett, Boss*, and *Christensen* into *In re Insulin*. (ECF No. 89.)

On March 29, 2018, Plaintiffs filed the First Amended Class Action Complaint against Defendants. (ECF No. 131.) On May 14, 2018, Defendants filed a Motion to Dismiss Plaintiffs' Complaint (ECF No. 158), comprised of a brief in support of dismissing Counts One through Five of the Complaint (ECF No. 158-1) and a separate brief in support of dismissing Counts Six through Fifty-Nine of the Complaint. (ECF No. 158-2.) On July 5, 2018, Plaintiff filed an Opposition to Defendants' Motion to Dismiss. (ECF No. 181.) On August 20, 2018, Defendants filed a Reply Brief to Plaintiffs' Opposition to the Motion to Dismiss. (ECF No. 190.)

#### II. Legal Standards

#### A. Rule 12(b)(6)

\*4 In deciding a motion to dismiss pursuant to Federal Rule of Civil Procedure 12(b)(6), a district court is "required to accept as true all factual allegations in the complaint and draw all inferences in the facts alleged in the light most favorable to the [plaintiff]." Phillips v. Cty. of Allegheny, 515 F.3d 224, 228 (3d Cir. 2008). "[A] complaint attacked by a Rule 12(b)(6) motion to dismiss does not need detailed factual allegations." Bell Atlantic Corp. v. Twombly, 550 U.S. 544, 555, 127 S.Ct. 1955, 167 L.Ed.2d 929 (2007) (citations omitted). However, the plaintiff's "obligation to provide the 'grounds' of his 'entitle[ment] to relief' requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action." *Id.* (citing *Papasan v. Allain*, 478 U.S. 265, 286, 106 S.Ct. 2932, 92 L.Ed.2d 209 (1986) ). A court is "not bound to accept as true a legal conclusion couched as a factual allegation." Papasan, 478 U.S. at 286, 106 S.Ct. 2932. Instead, assuming the factual allegations in the complaint are true, those "[f]actual allegations must be

enough to raise a right to relief above the speculative level." *Twombly*, 550 U.S. at 555, 127 S.Ct. 1955.

"To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to 'state a claim for relief that is plausible on its face." "Ashcroft v. Iqbal, 556 U.S. 662, 678, 129 S.Ct. 1937, 173 L.Ed.2d 868 (2009) (citing Twombly, 550 U.S. at 570, 127 S.Ct. 1955). "A claim has facial plausibility when the pleaded factual content allows the court to draw the reasonable inference that the defendant is liable for misconduct alleged." Id. This "plausibility standard" requires the complaint allege "more than a sheer possibility that a defendant has acted unlawfully," but it "is not akin to a probability requirement.' " Id. (quoting Twombly, 550 U.S. at 556, 127 S.Ct. 1955). "Detailed factual allegations" are not required, but "more than an unadorned, the defendant-harmed-me accusation" must be pled; it must include "factual enhancements" and not just conclusory statements or a recitation of the elements of a cause of action. Id. (citing Twombly, 550 U.S. at 555, 557, 127 S.Ct. 1955).

"Determining whether a complaint states a plausible claim for relief [is] ... a context-specific task that requires the reviewing court to draw on its judicial experience and common sense." *Iqbal*, 556 U.S. at 679, 129 S.Ct. 1937. "[W]here the well-pleaded facts do not permit the court to infer more than the mere possibility of misconduct, the complaint has alleged —but it has not 'show[n]'—'that the pleader is entitled to relief.' " *Id.* at 679, 129 S.Ct. 1937 (quoting Fed. R. Civ. P. 8(a)(2)). However, courts are "not compelled to accept 'unsupported conclusions and unwarranted inferences,' " *Baraka v. McGreevey*, 481 F.3d 187, 195 (3d Cir. 2007) (quoting *Schuylkill Energy Res. Inc. v. Pa. Power & Light Co.*, 113 F.3d 405, 417 (3d Cir. 1997)), nor "a legal conclusion couched as a factual allegation." *Papasan*, 478 U.S. at 286, 106 S.Ct. 2932.

While, as a general rule, the court may not consider anything beyond the four corners of the complaint on a motion to dismiss pursuant to Rule 12(b)(6), the Third Circuit has held that "a court may consider certain narrowly defined types of material without converting the motion to dismiss [to one for summary judgment pursuant to Rule 56]." *In re Rockefeller Ctr. Props. Sec. Litig.*, 184 F.3d 280, 287 (3d Cir. 1999). Specifically, courts may consider any "'document *integral to or explicitly relied upon* in the complaint.' "*In re Burlington Coat Factory Secs. Litig.*, 114 F.3d 1410, 1426 (3d Cir. 1997)

(quoting *Shaw v. Dig. Equip. Corp.*, 82 F.3d 1194, 1220 (1st Cir. 1996)).

#### **B. Rule 9(b)**

Pursuant to Federal Rule of Civil Procedure 9(b), when alleging fraud, "a party must state with particularity the circumstances constituting fraud or mistake, although intent, knowledge, and other conditions of a person's mind may be alleged generally." In re Lipitor Antitrust Litig., 868 F.3d 231, 249 (3d Cir. 2017) (citations omitted); see also U.S. ex rel. Moore & Co., P.A. v. Majestic Blue Fisheries, LLC, 812 F.3d 294, 307 (3d Cir. 2016) (holding that a "plaintiff alleging fraud must ... support its allegations with all of the essential factual background that would accompany the first paragraph of any newspaper story – that is, the who, what, when, where and how of the events at issue") (citations omitted). Accordingly, "a party must plead [its] claim with enough particularity to place defendants on notice of the 'precise misconduct with which they are charged." "United States ex rel. Petras v. Simparel, Inc., 857 F.3d 497, 502 (3d Cir. 2017) (quoting Lum v. Bank of Am., 361 F.3d 217, 223-24 (3d Cir. 2004), abrogated on other grounds by Bell Atl. Corp. v. Twombly, 550 U.S. 544, 557, 127 S.Ct. 1955, 167 L.Ed.2d 929 (2007)).

#### III. Decision

#### A. RICO Violation Claims

\*5 Defendants contend that this Court should dismiss Counts One and Two of Plaintiffs' Complaint, which allege violations of the Racketeer Influenced and Corrupt Organizations Act, 18 U.S.C. §§ 1961-1968 (1970) ("RICO"), asserting that Plaintiffs' claims are barred by the "indirect purchaser rule," do not plead facts amounting to mail or wire fraud, fail to plead a valid RICO enterprise, do not adequately plead proximate causation, and do not adequately plead a RICO conspiracy. (ECF No. 158-1 at 26-54.) Plaintiffs counter that the RICO claims should not be dismissed at this juncture because, inter alia, they have adequately pled each element of such violation and Supreme Court and Third Circuit precedent have consistently rejected Defendants' narrow interpretation of the indirect purchaser rule. (ECF No. 181 at 14-52.) For the reasons set forth below, this Court finds that Plaintiffs cannot sustain their RICO causes of action.

To demonstrate a violation of 18 U.S.C. § 1962(c), a plaintiff must prove:

"(1) the existence of an enterprise affecting interstate commerce; (2) that the defendant was employed by or associated with the enterprise; (3) that the defendant participated ..., either directly or indirectly, in the conduct or the affairs of the enterprise; and (4) that he or she participated through a pattern of racketeering activity."

*United States v. Bergrin*, 650 F.3d 257, 265 (3d Cir. 2011) (quoting *United States v. Irizarry*, 341 F.3d 273, 285 (3d Cir. 2003)).

Proving a violation of 18 U.S.C. § 1962(c) "requires no more than this." *Sedima, S.P.R.L. v. Imrex Co., Inc.*, 473 U.S. 479, 496 (1985).

#### i. RICO Elements

First, Defendants contend that Plaintiffs do not plead facts amounting to mail or wire fraud. (ECF No. 158-1 at 30.) Illicit racketeering activity includes "a host of so-called predicate acts, including 'any act which is indictable under ... Section 1341 [mail fraud].' " Bridge v. Phoenix Bond & Indem. Co., 553 U.S. 639, 647, 128 S.Ct. 2131, 170 L.Ed.2d 1012 (2008) (quoting 18 U.S.C. § 1961(1)(B) ). The Third Circuit has traditionally interpreted mail fraud statutes broadly. See United States v. Martinez, 905 F.2d 709, 715 (3d Cir.), cert. denied, 498 U.S. 1017, 111 S.Ct. 591, 112 L.Ed.2d 595 (1990). Fraud is "measured in a particular case by determining whether the scheme demonstrated a departure from fundamental honesty, moral uprightness, or fair play and candid dealings in the general life of the community." United States v. Riley, 621 F.3d 312, 327 n.19 (3d Cir. 2010) (citation omitted). However, without "a specific fraudulent statement" identifying "the time, place, speaker, and content" of the alleged misrepresentation, a civil RICO claim asserting fraud should be dismissed. Jaye v. Oak Knoll Vill. Condo. Owners Ass'n, Inc., 2016 WL 7013468, at \*15 (D.N.J. Nov. 30, 2016).

Plaintiffs have adequately pled mail and wire fraud. Plaintiffs allege Defendants committed mail and wire fraud by publishing artificially inflated AWPs via mail and interstate wire facilities. (ECF No. 131 ¶¶ 318-25.)<sup>5</sup> Plaintiffs further alleged Defendants knew that AWP is a pricing index and that purchasers pay for analog insulin based on that index. (ECF

No. 131 ¶¶ 253-62, 323, 325.) Federal courts have held that excessive inflation of prices on an index, such as the AWPs in this matter, may constitute mail and wire fraud. See In re Lupron® Mktg. & Sales Practices Litig., 295 F.Supp.2d 148, 165-68 (D. Mass. 2003); see also Schmuck v. United States, 489 U.S. 705, 710-11, 109 S.Ct. 1443, 103 L.Ed.2d 734 (1989). Defendants' reliance on Langford v. Rite Aid of Alabama, Inc., 231 F.3d 1308, 1313-14 (11th Cir. 2000) and Bonilla v. Volvo Car Corp., 150 F.3d 62, 71 (1st Cir. 1998) is misplaced. As Plaintiffs highlight in their brief, this is not a matter of nondisclosure. (ECF No. 181 at 19.) Rather, Plaintiffs allege that Defendants committed fraud by "[holding] out their artificially increased AWPs as benchmark prices, fully aware that AWP is a pricing index intended to approximate the true cost of a drug." (Id.) Plaintiffs further contend that the AWP had no reasonable relationship to the actual price of the drugs, and that Defendants knew of this fraud. (ECF No. 131 ¶¶ 176-178, 254.) Accordingly, Plaintiffs have adequately pled mail and wire fraud.

- Specifically, Plaintiffs allege "[t]he Defendant Drug Manufacturers intended that the PBMs would (and did) distribute, through the U.S. mail and interstate wire facilities, promotional and other materials which claimed that rebates saved health care payers and consumers like the plaintiffs and class members money on their prescription needs." (ECF No. 131 ¶ 321(f).)
- \*6 Second, Defendants contend Plaintiffs failed to plead a valid RICO enterprise. (ECF No. 158-1 at 41.) An essential feature of an association-in-fact enterprise is the sharing of a "common purpose" between the members. United States v. Boyle, 556 U.S. 938, 948, 129 S.Ct. 2237, 173 L.Ed.2d 1265 (2009). "From the terms of RICO, it is apparent that an association-in-fact enterprise must have at least three structural features: a purpose, relationships among those associated with the enterprise, and longevity sufficient to permit the enterprise's purpose." *Id.* at 946, 129 S.Ct. 2237.6 The Third Circuit has held that *Boyle's* construction of the term "association-in-fact enterprise" is "capacious," "expansive," and "obviously broad." In re Ins. Brokerage Antitrust Litig., 618 F.3d 300, 366 (3d Cir. 2010). Additionally, a valid RICO enterprise requires "defendants [to] conduct[] or participat[e] in the conduct of the 'enterprise's affairs,' not just their own affairs." Reves v. Ernst & Young, 507 U.S. 170, 185, 113 S.Ct. 1163, 122 L.Ed.2d 525 (1993) (quoting 18 U.S.C. § 1962(c)).
- The Supreme Court has also defined an association-inenterprise, for RICO purposes, as "a group of persons

associated together for a common purpose of engaging in a course of conduct." United States v. Turkette, 452 U.S. 576, 583, 101 S.Ct. 2524, 69 L.Ed.2d 246 (1981).

Plaintiffs have adequately pled a valid RICO enterprise. Indeed, Plaintiffs' Complaint alleged a common fraudulent purpose between the Defendants, provided a motive for such purpose, and detailed the alleged relationships between the Defendants. (ECF No. 131 ¶¶ 254, 302-09, 334-35.) $^{7}$ Moreover, Plaintiffs also point out that the Amended Complaint satisfies the participation prong by virtue of their allegation that Novo and Sanofi both accomplished "something more" that would be unlikely absent collusion: preferred formulary status without real price reductions. (ECF No. 181 at 48-49.)

7 Specifically, Plaintiffs allege that "[e]ach manufacturer-PBM Enterprise also shares a common purpose of perpetuating use of insulin benchmark prices as the basis for consumer cost-sharing and out-of-pocket payments in the pharmaceutical industry ... these corporations would not be able to market large spreads to PBMs in exchange for formulary positions without the use of the inflated benchmark prices as the basis for consumer cost-sharing and out-of-pocket payments in the pharmaceutical industry." (ECF No. 131 ¶ 302.) Plaintiffs further alleged that "[e]ach of the Manufacturer-PBM Insulin Pricing Enterprises has a systemic linkage because there are contractual relationships, financial ties, and continuing coordination of activities between each Defendant Drug Manufacturer and each PBM that is an associate." (ECF No. 131 ¶ 303.)

Defendants' contentions that Plaintiffs have failed to adequately plead a valid RICO enterprise are without merit. Defendants contend that PBMs and manufacturers cannot have a common purpose in the RICO enterprise because they play different roles in the distribution chain (ECF No. 158-1 at 42-43.) However, Defendants' construction of the common fraudulent purpose prong is too narrow, as federal courts have held that allegations of falsely inflated AWPs may "provide a plausible common fraudulent purpose." In re Pharm. Indus. Average Wholesale Price Litig., 307 F.Supp.2d 196, 206 (D. Mass. 2004). Defendants also argue that Plaintiffs have not adequately pled that Defendants participated in the affairs of the alleged enterprise, contending that the allegations are "entirely consistent with [defendants and the PBMs] each going about their own business." United Food & Commercial Workers Unions & Emp'rs Midwest Health Benefits Fund v. Walgreen Co., 719 F.3d 849, 855 (7th Cir. 2013). On the contrary, Plaintiffs have alleged conduct that would not occur in competition for business in a legitimate market. See id. at 856. As such, Plaintiffs adequately alleged a valid RICO enterprise.

\*7 Third, Defendants contend that Plaintiffs failed to adequately plead proximate causation. A sustainable RICO claim requires proximate causation. In re Avandia Marketing, Sales Practices & Product Liability Litigation, 804 F.3d 633, 638 (3d Cir. 2015). "[T]o state a claim under civil RICO, the plaintiff is required to show that a RICO predicate offense 'not only was a but for cause of his injury, but was the proximate cause as well.' " Hemi Group, LLC v. City of New York, 559 U.S. 1, 9, 130 S.Ct. 983, 175 L.Ed.2d 943 (2010) (quoting Holmes v. Sec. Inv'r Prot. Corp., 503 U.S. 258, 268, 112 S.Ct. 1311, 117 L.Ed.2d 532 (1992)). If a plaintiff's alleged injuries "could have resulted from factors other than [the defendants'] alleged acts of fraud," there is no proximate causation. Anza v. Ideal Steel Supply Corp., 547 U.S. 451, 459, 126 S.Ct. 1991, 164 L.Ed.2d 720 (2006).

Plaintiffs have adequately plead proximate causation. Although Plaintiffs assert that the costs were passed down to them, they explicitly allege that their injuries would not have occurred "[b]ut for the misrepresentations that the Defendant Drug Manufacturers made regarding the benchmark prices of their analog insulins" as the inflated AWP prices forced the intermediaries to raise their prices so as to not suffer the out-of-pocket overcharges alleged in the suit. (ECF No. 131 ¶¶ 339-40.) Defendants assert that Plaintiffs "cannot show the direct relationship required to establish proximate causation," (ECF No. 158-1 at 50), however, the allegation that the cost is borne by the "end payor" is sufficient to establish proximate causation in this context. In re Pharm. Indus. Average Wholesale Price Litig., 295 F.Supp.2d at 175. Proximate causation in the RICO context requires "some direct relation between the injury asserted and the injurious conduct alleged," Holmes, 503 U.S. at 268, 112 S.Ct. 1311, and the Amended Complaint makes such allegations.

Finally, Defendants assert that Plaintiffs have not adequately pled a RICO conspiracy. (ECF No. 158-1 at 51.) In order to adequately plead a RICO conspiracy, Plaintiffs must "allege facts suggesting that [the defendants] knowingly agreed to facilitate any illegal scheme." Mason v. Campbell, 2016 WL 8716458, at \*6 (E.D. Pa. July 29, 2016) (citing Twombly, 550 U.S. at 570, 127 S.Ct. 1955). "[E]vidence of parallel conduct by alleged co-conspirators is not sufficient to show an agreement." In re Ins. Brokerage, 618 F.3d at 321. Rather, allegations of parallel conduct "'must be placed in a context

that raises a suggestion of a preceding agreement, not merely parallel conduct that could just as well be independent action.' " *Id.* at 322 (quoting *Twombly*, 550 U.S. at 557, 127 S.Ct. 1955).

Plaintiffs have adequately pled a RICO conspiracy. Plaintiffs do not merely allege parallel conduct, but rather assert facts that suggest a preceding agreement. Plaintiffs assert not only that Defendants "agree[d] and conspir[ed] to violate 18 U.S.C. § 1962(c)" (ECF No. 131 ¶ 346), but also allege separate conspiracies of pricing enterprises between Novo and Sanofi and each PBM: CVS, Express Scripts, and OptumRx. (ECF No. 131 ¶¶ 310-12.) These allegations clearly suffice for a RICO conspiracy, and as such, Plaintiffs have adequately pled the existence of a RICO conspiracy.

#### ii. The Indirect Purchaser Rule

Next, Defendants assert Plaintiffs lack standing to pursue their RICO claim because they are "three levels down the distribution chain" from Defendants and are therefore "classic indirect purchasers" pursuant to the indirect purchaser rule doctrine established by the Supreme Court in Illinois Brick Co. v. Illinois, 431 U.S. 720, 97 S.Ct. 2061, 52 L.Ed.2d 707 (1977) and Kansas v. UtiliCorp United Inc., 497 U.S. 199, 110 S.Ct. 2807, 111 L.Ed.2d 169 (1998). (ECF No. 158-1 at 26-27.) Plaintiffs argue that applying the indirect purchaser rule – an antitrust law principle – to RICO claims of fraudulent pricing runs contrary to Supreme Court precedent, and that, in any event, Plaintiffs were directly harmed as they paid prices based on Defendants' fraudulent AWPs, irrespective of the prices paid by intermediaries in the distribution chain. (ECF No. 181 at 31-32.) On January 17, 2019, this Court held oral argument on the limited issue of the applicability of the indirect purchaser rule to Plaintiffs' RICO claims.

\*8 The Supreme Court developed the indirect purchaser rule in the antitrust context, when it held that Clayton Act plaintiffs may not demonstrate injury by providing evidence only of indirect purchases. *Illinois Brick*, 431 U.S. at 737, 97 S.Ct. 2061. The Court warned that allowing indirect purchasers to recover under such a theory would "transform trebledamages actions into massive multiparty litigations involving many levels of distribution and including large classes of ultimate consumers remote from the defendant." *Id.* at 739, 97 S.Ct. 2061. Moreover, the indirect purchaser rule was also intended to prevent defendants from being exposed to

"multiple liability" should both indirect and direct purchasers in a distribution chain be permitted to assert claims arising out of a single overcharge. *McCarthy v. Recordex Serv., Inc.*, 80 F.3d 842, 851 (3d Cir. 1996). Because 18 U.S.C. § 1964(c), RICO's private cause of action, was modeled on the Clayton Act, "antitrust standing principles apply equally to allegations of RICO violations." *McCarthy*, 80 F.3d at 855; *see also Holmes*, 503 U.S. at 270-74, 112 S.Ct. 1311.

Defendants argue Plaintiffs "do not, and cannot, allege that they purchase analog insulin directly from any defendant," (ECF No. 158-1 at 39), citing the Complaint's allegation that Defendants' products are sold "from manufacturers to wholesaler, wholesaler to retailer (or mail order), and retailer to patient." (*Id.*) In support of its argument, Defendants cite this District's decision in *Hale v. Stryker Orthopaedics*, 2009 WL 321579 at \*3 (D.N.J. Feb. 9, 2009), which dismissed a plaintiff's RICO complaint where the plaintiffs did "not plead that they purchased [the products] directly from [the defendants]." The *Hale* court determined that a plaintiffs' co-payment alone does not confer standing upon it as several actors stood in the distribution chain between the plaintiffs and the defendants. *Id* at \*4, 130 S.Ct. 983.

Although Plaintiffs advocated competently against applying the indirect purchaser rule in this case, this Court is bound by the controlling caselaw and thus concludes Plaintiffs' Complaint has not sufficiently pled allegations to withstand Defendants' indirect purchaser rule challenge. Plaintiffs' Complaint merely alleges that Defendants' artificial price inflation of the AWPs caused them to pay an increased price for analog insulin, yet never alleges that such overpayments were made directly to Defendants. Specifically, Plaintiffs assert:

336.... [W]hen a plaintiff or class member fills a prescription for one of the analog insulins, she is responsible for paying all or a portion of the medication's cost. If the plaintiff or class member is uninsured, she must pay 100% of the drugs' point-of-sale prices, which are based on the Defendant Drug Manufacturers' benchmark prices. If the plaintiff or class member has a high-deductible health plan, she must pay 100% of the drugs' point-of-sale prices, based on Defendant Drug Manufacturers' benchmark prices, until she satisfies her deductible. If the plaintiff's or class member's health plan contains a coinsurance requirement, she is responsible for paying a percentage of her drugs' point-of-sale prices, based on the Defendants Drug Manufacturers' benchmark

prices. And if the plaintiff or class member is a member of a Medicare Part D plan, she is responsible for paying all or a portion of her drugs' point-of-sale prices based on Defendant Drug Manufacturers' benchmark prices, until she reaches her maximum contribution.

337. The amount of each of these cash payments is based on the Defendant Drug Manufacturers' benchmark prices. Therefore, when each Defendant Drug Manufacturer artificially inflated each analog insulin's benchmark price and then used each Manufacturer-PBM Insulin Pricing Enterprises to sell those analog insulins, they also artificially inflate plaintiffs' and class members' out-of-pocket expenses.

338. The plaintiffs' and class members' damages are therefore the difference between the defendants' reported benchmark prices and the net prices at which they sell their analog insulins for all plaintiff and class member out-of-pocket expenses.

\*9 339. Plaintiffs' injuries, and those of the class members, were proximately caused by the Defendant Drug Manufacturers' racketeering activity. But for the misrepresentations that the Defendant Drug Manufacturers made regarding the benchmark prices of their analog insulins and the scheme that the Manufacturer-PBM Insulin Pricing Enterprises employed, plaintiffs and others similarly situated would have paid less, out-of-pocket, for their analog insulins.

(ECF No. 131 ¶¶ 336-39.)

Plaintiffs' core allegation is that Defendants engaged in a scheme to "artificially inflat[e] the benchmark prices of their analog insulin." (ECF No. 131 at ¶ 20.) However, Plaintiffs concede that they, the consumers, are not the first party to pay for the analog insulin at a purportedly inflated price. Rather, Plaintiffs outline a scheme whereby the analog insulins are sold to wholesalers at prices "based on the benchmark prices that are set by the manufacturers," and are subsequently sold to pharmacies, hospitals, and clinics at prices approximating the benchmark prices. (ECF No. 131 at ¶¶ 164, 176.) As such, Plaintiffs are multiple purchasers down the distribution chain from Defendants and are quintessential indirect purchasers for the purposes of the indirect purchaser rule. See McCarthy, 80 F.3d at 848 (holding that "only the purchaser immediately downstream from the alleged [RICO violator]" possesses standing to pursue an action).

Plaintiffs contend the indirect purchaser rule does not vitiate their RICO standing as the rule does not apply to RICO claims, and that Defendants' alleged fraud directly injured Plaintiffs as Defendants set the AWPs that ultimately dictated the price paid by the Plaintiffs, thereby conferring upon them RICO standing. (ECF No. 181 at 30-36.) Plaintiffs posit the Complaint explains the process by which Plaintiffs pay out-of-pocket costs, and thus suffer a direct injury based directly on the prices set by Defendants. (ECF No. 131 ¶ 260-69.) This Court is not persuaded by Plaintiffs' arguments. In *McCarthy*, the Third Circuit unequivocally held that the indirect purchaser rule applies to RICO claims, stating "the central and dispositive issue [in a RICO action] is whether plaintiffs are 'direct purchasers.' If so, they are entitled to pursue ... their ... RICO claims." *McCarthy*, 80 F.3d at 855.

At oral argument, Plaintiffs urged this Court to rely on Avandia, 804 F.3d at 638, to the extent it conflicts with McCarthy with respect to the applicability of the indirect purchaser rule in RICO actions. Though Avandia is the more recent Third Circuit decision, the facts of this matter are meaningfully distinguishable such that Avandia does not provide persuasive support to Plaintiffs' position. Plaintiffs assert the Avandia plaintiffs were "third party payors" who "did not directly purchase [the product] from the manufacturer ... but instead reimbursed a pharmacy that purchased [the product] in the chain of distribution." (ECF No. 181 at 35.) Plaintiffs contend that because the "distribution chain did not preclude the RICO claim" and because "the issue was whether the pharmaceutical company's misrepresentations directly caused the health insurers to pay a higher rate than they otherwise would have," its Complaint should be permitted to proceed as it alleges the "same conduct forming the basis of the RICO scheme." (ECF No. 181 at 35-36.) This Court disagrees.

Unlike here, the *Avandia* plaintiffs were not seeking recourse pursuant to payments made to third parties based on allegedly fraudulent prices set by a manufacturer. *Avandia* did not concern an identical case of an indirect purchaser. Rather, the *Avandia* plaintiffs' cause of action was couched in the defendants' alleged failure to disclose known health risks of various drugs ultimately included in their formularies, as the court explained:

\*10 The conduct that allegedly caused plaintiffs' injuries is the same conduct forming the basis of the RICO scheme alleged in the complaint – the misrepresentation of the heart-related risks of taking Avandia that caused TPPs and PBMs to place Avandia in the formulary. The injury alleged

by the TPPs is an economic injury independent of any physical injury suffered by Avandia users. And, as far as we can tell, prescribing physicians did not suffer RICO injury from [the] marketing of Avandia.

Avandia, 804 F.3d at 644.

The Avandia plaintiffs were third-party payors who included the product, Avandia, in their formulary decisions at favorable rates in direct reliance on material misrepresentations made by the defendant, a pharmaceutical company. Avandia, 804 F.3d at 636.8 By contrast, Plaintiffs allege their damages stem from artificially inflated AWPs paid by wholesalers and pharmacies before the consumers make their purchasers from those intermediaries. See Warren Gen. Hosp. v. Amgen Inc., 643 F.3d 77, 95 (3d Cir. 2011) (holding that the indirect purchaser rule applies to prescription drug sales and noting that "[b]ecause of the complicated interplay between market forced, the possibility that the wholesaler was harmed by defendant's actions exists even if the majority of the injury is borne by the indirect purchaser").

Similarly, Plaintiffs' reliance on the Second Circuit's decision in *Desiano v. Warner-Lambert Co.*, 326 F.3d 339 (2d Cir. 2003) is also misplaced. (ECF No. 181 at 36.) *Desiano* concerned an antitrust action to recover alleged overpayments made to a drug manufacturer, however, unlike in this matter, the relief sought included "only the portion of the prescription paid [directly] by the [healthcare providers] and exclude[d] the part paid by the patients, in the form of a 'co-pay.' "*Id.* at 345.

At oral argument, Plaintiffs also cited a recent decision from the District of Kansas, *In re Epipen*, 336 F. Supp. 3d 1259 (D. Kan. 2018), in further support of its position that the indirect purchaser rule should not bar its RICO claim. (Ps' Ltr. (ECF No. 244).) Plaintiffs contend the *Epipen* court relied on Supreme Court decisions in *Holmes* and *Bridge v. Phoenix Bond & Indem. Co.*, 553 U.S. 639, 128 S.Ct. 2131, 170 L.Ed.2d 1012 (2008) in declining to extend the indirect purchaser rule to a RICO action with a similar fact pattern. (*Id.*) This Court disagrees with Plaintiffs' assertions. *Holmes* explicitly held that federal jurisprudence interpreting antitrust principles govern RICO claims because Congress modeled RICO's civil action provision on a substantially similar provision in the Clayton Act, stating:

The key to better interpretation lies in some statutory history. We have repeatedly observed, *see Agency Holding Corp. v. Malley-Duff & Assocs., Inc.*, 483 U.S. 143, 150-51, 107 S.Ct. 2759, 97 L.Ed.2d 121 (1987) ... that Congress

modeled § 1964(c) ... [of RICO after] the federal antitrust laws, § 4 of the Clayton Act ...

In Associated General Contractors ... we discussed how Congress enacted § 4 in 1914 with language borrowed from § 7 of the Sherman Act, passed 24 years earlier. Before 1914, lower federal courts had read § 7 to incorporate common-law principles of proximate causation ... and as we reasoned, as many lower federal courts had done before us ... that congressional use of the § 7 language in § 4 presumably carried the intention to adopt 'the judicial gloss that avoided a simple literal interpretation.' ... Thus, we held that a plaintiff's right to sue under § 4 required a showing that the defendant's violation not only was a 'but for' cause of his injury, but was the proximate cause as well.

\*11 The reasoning applies just as readily to § 1964(c) [of RICO]. We may fairly credit the 91st Congress, which enacted RICO, with knowing the interpretation federal courts had given the words earlier Congresses had used first in § 7 of the Sherman Act, and later in the Clayton Act's § 4.... It used the same words, and we can only assume it intended them to have the same meaning that courts had already given them.

Holmes, 503 U.S. at 267-68, 112 S.Ct. 1311.

Nothing in Holmes undercuts the voluminous federal jurisprudence determining that courts may apply the indirect purchaser rule to RICO actions with the same force as under antitrust law. <sup>9</sup> The *Epipen* court's discussion of *Holmes* merely suggests *Holmes* did not create a bright line applying the indirect purchaser rule to all RICO actions with the same force as in the antitrust context, stating "the Court has 'cautioned our use of the term "direct" should merely be understood as a reference to the proximate cause enquiry that is informed by the concerns set out in the text." "Epipen, 336 F.Supp.3d at 1324 (quoting Holmes, 503 U.S. at 269 n.15, 112 S.Ct. 1311). The court in *Epipen* continued to note "the Supreme Court has recognized that 'the infinite variety of claims that may arise [under RICO] make it virtually impossible to announce a black-letter rule that will dictate the result in every case' for determining whether an alleged RICO violation was the proximate cause of plaintiff's injuries." Epipen, 336 F.Supp.3d at 1324-25 (quoting Holmes, 503 U.S. at 272 n.20, 112 S.Ct. 1311).

Additionally, this Court disagrees with Plaintiffs' reliance on *Sedima*, 473 U.S. at 498-99, 105 S.Ct. 3275. Although *Sedima* postulates that "RICO is evolving into something quite different from the original conception

of its enactors," *id.* at 500, 105 S.Ct. 3275, and even suggests that interpreting its elements in identical fashion to those under antitrust law may play a role in such evolution, *id.* at 498-99, 105 S.Ct. 3275, it does not at all mention the indirect purchaser rule and certainly provides no analysis tending to suggest a preference that such rule not be applied in the RICO context.

Similarly, the Supreme Court's holding in Bridge does not preclude the application of the indirect purchaser rule to Plaintiffs' RICO claims. Bridge merely held that plaintiffs who are injured "by reason of" a pattern of mail fraud may have RICO standing "even if he [or she] has not relied on any misrepresentations." Bridge, 553 U.S. at 649-50, 128 S.Ct. 2131. Unlike here, Bridge does not concern the case of an indirect purchaser and does not stand for the proposition that plaintiffs multiple levels down the consumer chain may possess RICO standing despite the indirect purchaser rule. The disparity between the holding in Epipen and the Third Circuit decisions is best explained by the conflicting application of the indirect purchaser rule between the Third and Tenth Circuits. The Epipen court readily admitted the Third Circuit recognizes the indirect purchaser rule in the RICO context, whereas the Tenth Circuit does not, explaining:

Because defendants just cite cases from outside the Tenth Circuit to support their argument that indirect purchasers lack RICO standing, the court declines to apply that rule here. Instead, applying the guidance from our Circuit in *Safe Streets* [Alliance v. Hickenlooper, 859 F.3d 865 (10th Cir. 2017)], the court already has determined that the class plaintiffs adequately have alleged that defendants' RICO violations proximately caused their injuries.

#### \*12 ...

And just as importantly, defendants cite no cases from the Tenth Circuit holding that a RICO plaintiff lacks standing to assert a claim for overpaying for pharmaceuticals when the plaintiff receives the benefit of the bargain in the form of purchasing effective drugs, even at inflated prices. The court declines to apply the holdings from the District of New Jersey cases here, as defendants urge.

Epipen, 336 F.Supp.3d at 1325-26.

Finally, Plaintiffs' contentions that they suffered direct injury as a result of Defendants' artificially inflated AWPs, thereby conferring RICO standing, are also without merit. (ECF No. 181 at 32.) Plaintiffs argue the consumers' place in the chain of distribution in irrelevant because "the plaintiffs pay prices *directly* based on the defendants' fraudulent AWPs

irrespective of the prices other intermediaries within the chain pay." (Id.) Plaintiffs further assert that Defendants' potential overcharges of intermediaries are inconsequential as "[t]he issue is that the defendant[] grossly misrepresented the pricing benchmarks used to directly set consumer prices." (Id.) However, such is still insufficient to overcome the indirect purchaser rule.

The Amended Complaint explicitly describes the distribution chain and flow of revenue therein: first, Defendants sell analog insulin to wholesalers at prices "based on benchmark prices that are set by manufacturers" (ECF No. 131 ¶ 176); second, wholesalers earn a margin by selling insulin to pharmacies at approximately the same prices as the benchmarks prices set (ECF No. 131 ¶¶ 164, 167-68); and third, pharmacies earn a margin by charging benchmarkbased prices, which are set by bargaining between the pharmacy and PBMs (in the case of insured consumers) or unilaterally by the pharmacy (in the case of uninsured consumers). (ECF No. 131 ¶¶ 179, 181, 201). Notably, Plaintiffs do not allege that Defendants invariably set the direct prices paid by consumers, but instead that those prices are sometimes determined after certain negotiations between intermediaries in the distribution chain who subsequently impose various mark-ups. (Id.)

Although Plaintiffs do allege the benchmark prices "directly" affect the price paid by consumers (ECF No. 181 at 32), such would be insufficient to overcome the indirect purchaser rule bar to RICO standing. The indirect purchaser rule still applies even when the alleged improper price inflation is passed to a plaintiff on a "dollar for dollar basis." *McCarthy*, 80 F.3d at 853. <sup>10</sup> The Plaintiffs have merely alleged a pass-through of the inflated price from one of the various intermediaries to the consumers. Such allegations cannot overcome an indirect purchaser rule challenge.

McCarthy notes "the fact that the [subject costs] were passed on [from an intermediary] to [the plaintiffs] on a dollar for dollar basis ... is not dispositive. Indeed, the subcontractors in Illinois Brick and the utility companies in Utilicorp passed on their costs to the plaintiffs in those respective cases; yet the Supreme Court deemed this fact insufficient to confer standing to the indirect-purchaser plaintiffs in those cases." 80 F.3d at 853.

\*13 The facts of this case closely mirror those of *Hale*. 2009 WL 321579. In *Hale*, plaintiffs asserted RICO violations pursuant to the defendants' alleged artificial price inflation of hip and knee implant devices. *Id.* at \*1. As in this matter,

the *Hale* plaintiffs failed to allege they directly purchased the subject products from the defendants. *Id.* at \*4. Rather, the plaintiffs pled only that they suffered a direct injury evidenced by heightened coinsurance payments passed down to them through the distribution chain. Accordingly, the *Hale* court determined that the plaintiffs lacked RICO standing pursuant to the indirect purchaser rule, stating:

While Plaintiffs argue that they have pled direct injury since they paid artificially-inflated coinsurance payments for their surgeries, Plaintiffs have not alleged that they were direct purchasers of the replacement joints manufactured by Defendants. Between Plaintiffs and Defendants in the chain of distribution stand several actors, including the hospitals performing the joint surgeries and Plaintiffs' insurers. The chain of distribution squarely presents the multiple liability and damage apportionment risks discussed in *McCarthy*. Thus, Plaintiffs' co-payment alone does not allow them to stand in the shoes of a direct purchaser for standing purposes.

...

After carefully considering the arguments put forth by both sides, it seems clear that under the facts as pled, Plaintiffs cannot escape the bar of the "direct purchaser" rule. To do so, Plaintiffs would have to plead that they bought their implants directly from Defendants. Since Plaintiffs have not so pled, they lack standing under these facts to bring their RICO claims.

Id.

Although Plaintiffs allege injury not only through heightened coinsurance payments, but also via fraudulent AWPs that "directly set consumer prices" (ECF No. 181 at 32), Plaintiffs have failed to plead any direct purchase between themselves and Defendants. The chain of distribution alleged in this matter is fatal to Plaintiff's RICO claim, and as in *Hale*, such distribution chain "squarely presents the multiple liability and damage apportionment risks discussed in *McCarthy.*" *Id.* Allowing Plaintiffs' RICO claims to proceed would expose Defendants to liability to Plaintiffs as well as to the various direct purchasers, such as the wholesalers and PBMs, thereby allowing to persist the exact harm that the indirect purchaser rule seeks to prevent.

Finally, in a February 5, 2019 letter brief (ECF No. 249), Plaintiffs urged this Court to follow a recent decision from this District, *In re Mercedes-Benz Emission Litig.*, No. 16-881, 2019 WL 413541 (D.N.J. Feb. 1, 2019), in which the

court allowed RICO claims to persist despite the fact that the plaintiffs did not directly purchase the product, luxury automobiles, directly from the manufacturers. *Mercedes-Benz* is distinguishable from this case. Although the *Mercedes-Benz* plaintiffs were not direct purchasers, that matter did not concern overpayments made to and by intermediaries, as here. Rather, *Mercedes-Benz* dealt primarily with proximate causation in the RICO context, a separate requirement. The court was not confronted with an indirect purchaser challenge to plaintiffs' standing, it was not briefed on the indirect purchaser rule, and it did not perform an analysis of the indirect purchaser rule whatsoever. *Id.* at \*18-26.

Although Plaintiffs have adequately pled the various elements of a RICO claim, they failed to allege that they directly purchased the analog insulin from Defendants. Rather, Plaintiffs claim injury by virtue of inflated prices of their downstream purchase. Therefore, Plaintiffs' claims are barred by the indirect purchaser rule, and as such, Plaintiffs lack standing to maintain this action pursuant to RICO. Accordingly, Defendants' Motion to Dismiss Plaintiffs' Amended Complaint is **GRANTED WITHOUT PREJUDICE** as to Counts One and Two.

#### **B.** New Jersey Consumer Fraud Act

\*14 Defendants contend that this Court should dismiss Counts Three, Four, and Five of the Plaintiffs' Complaint, which allege violations of the NJCFA, asserting that the Plaintiffs' Complaint fails to plead the deceptive practices and unconscionable pricing claims with specificity, does not plead unlawful conduct, and does not allege that Plaintiffs suffered any ascertainable loss. (ECF No. 158-1 at 54-60.) Plaintiffs counter that the Complaint plausibly pleads all necessary elements on an NJCFA claim. (ECF No. 181 at 52-59.) For the reasons set forth below, this Court finds that Plaintiffs have adequately pled an NJCFA claim.

The New Jersey Consumer Fraud Act, N.J.S.A. § 56:8-1, et seq. ("NJCFA") states, in pertinent part:

The act, use or employment by any person of any unconscionable commercial practice, deception, fraud, false pretense, false promise, misrepresentation, or the knowing, concealment, suppression, or omission of any material fact with intent that others rely upon such concealment, suppression or omission, in connection with the sale or advertisement of any merchandise or real estate,

or with the subsequent performance of such person as aforesaid, whether or not any person has in fact been misled, deceived or damaged thereby, is declared to be an unlawful practice; ....

N.J.S.A. § 56:8-2.

Courts have interpreted this section to require the following three elements to state a cause of action under the NJCFA: "1) unlawful conduct by defendant; 2) an ascertainable loss by plaintiff; and 3) a causal relationship between the unlawful conduct and the ascertainable loss." *Bosland v. Warnock Dodge, Inc.*, 197 N.J. 543, 964 A.2d 741, 749 (N.J. 2009) (citing *Int'l Union of Operating Eng'rs Local No. 68 Welfare Fund v. Merck & Co., Inc.*, 192 N.J. 372, 929 A.2d 1076, 1086 (N.J. 2007) ).

#### i. Specificity

Defendants assert Plaintiffs' Complaint does "not identify with specificity how defendants purportedly violated the NJCFA," and that as such, the Complaint lacks the particularity and specificity required by Rule 9(b) to withstand a motion to dismiss. (ECF No. 158-1 at 54.) The heightened pleading standard set forth in Rule 9(b) applies to a plaintiff's NJCFA claim. See Dewey v. Volkswagen, 558 F.Supp.2d 505, 524 (D.N.J. 2008) (applying Rule 9(b) to a NJCFA and common law fraud claims); see also DeGennaro v. Am. Bankers Ins. Co. of Fla., 2017 WL 2693881, at \*5 (D.N.J. June 22, 2017). To satisfy the specificity requirement of Rule 9(b), "the pleadings must state what the misrepresentation was, what was purchased, when the conduct complained of occurred, by whom the misrepresentation was made, and how the conduct led plaintiff to sustain an ascertainable loss." Smajlaj v. Campbell Soup Co., 728 F. Supp. 2d 84, 104 (D.N.J. 2011).

Plaintiffs' Complaint makes the necessary, specific allegations to withstand Defendants' Motion to Dismiss. The Complaint alleges misrepresentation in that Defendants warranted that the artificially inflated publicly reported benchmark prices of Novolog, Levemir, Apidra, Lantus, and Toujeo were the reasonable approximations of the true cost (ECF No. 131 ¶¶ 359-63, 379-83). Moreover, the Complaint also alleges that Plaintiffs purchased the subject drugs (*Id.* ¶¶ 355, 375), provides allegations concerning when the conduct occurred. (*Id.* ¶¶ 234-37), and asserts that the conduct led Plaintiffs to suffer a loss. (*Id.* ¶¶ 372-73, 392-93, 403-04).

Accordingly, the allegations in Plaintiffs' Complaint are pled with sufficient specificity.

#### ii. Unlawful Conduct

Defendants assert Plaintiffs' Complaint has "failed to plead any unlawful conduct by defendants" in that it fails "to identify any actions of defendants that were capable of misleading consumers as to analog insulin pricing or rebates" (ECF No. 158-1 at 55), and that as such, it cannot withstand this Motion to Dismiss. "The [NJCFA] creates three categories of unlawful practices: affirmative acts, knowing omissions, and violations of state regulations." Maniscalo v. Brother Int'l Corp. (USA), 627 F.Supp.2d 494, 499 (D.N.J. 2009) (quoting *Vukovich v. Haifa*, No. 03-737, 2007 WL 655597, \*9 (D.N.J. Feb. 27, 2007) (citing Cox v. Sears Roebuck & Co., 138 N.J. 2, 647 A.2d 454 (N.J. 1994) ) ). Affirmative acts require no showing of intent on behalf of the defendant. See Fenwick v. Kay Am. Jeep, Inc., 72 N.J. 372, 371 A.2d 13, 16 (N.J. 1977), "Thus, a defendant who makes an affirmative misrepresentation is liable even in the absence of knowledge of the falsity of the misrepresentation, negligence or the intent to deceive." Vukovick, 2007 WL 655597, at \*9 (citation omitted). "In contrast, when the alleged consumer fraud consists of an omission, a plaintiff must show that the defendant acted with knowledge, thereby making intent an essential element of the fraud." Id. Notably, unlawful acts expressly regulated by other statutes, regulations, or rules not promulgated under the NJCFA can also give rise to an NJCFA claim. See Henderson v. Hertz Corp., No. L-6937-03, 2005 WL 4127090, at \*5 (N.J. Super. Ct. App. Div. June 22, 2006); see also Lemelledo v. Beneficial Mgmt. Corp. of Am., 150 N.J. 255, 696 A.2d 546, 551-55 (N.J. 1997).

\*15 Additionally, the NJCFA "prohibit[s] business practices that are unfair or unconscionable *in addition to* practices that are fraudulent, deceptive, or misleading; these terms are defined separately and differently in the text of the statutes and in relevant case law interpreting them." *Cottrell v. Alcon Labs.*, 874 F.3d 154, 166 (3d Cir. 2017) (citations omitted). "There is no precise formulation for an 'unconscionable' act that satisfies the statutory standard for an unlawful practice." *D'Agostino v. Maldonado*, 96 N.H. 447, 78 A.2d 527, 537 (N.J. 2013). Rather, the NJCFA "establishes 'a broad business ethic' applied 'to balance the interest of the consumer public and those of the sellers.' " *Id.* (quoting *Kugler v. Romain*, 58 N.J. 522, 279 A.2d 640, 652 (N.J. 1971)).

Plaintiffs' Complaint adequately pled unlawful conduct in violation of the NJCFA. New Jersey courts have interpreted NJCFA's reach expansively, and in light of the applicable jurisprudence, Plaintiffs have adequately pled unconscionable conduct. Specifically, the Complaint alleges that Defendants knew, but did not disclose, the benchmark prices it selected for the various drugs it manufactures, and then offered the price spreads to PBMs in exchange for favorable placement on formularies. (ECF No. 131 ¶¶ 360, 380.) Additionally, Plaintiffs adequately pled unfair business practices in their assertions that Defendants' artificially inflated AWPs thereby causing gross overpayments among the most vulnerable members of society. (ECF No. 131 ¶¶ 267-71.) Accordingly, Plaintiffs' Complaint has adequately pled unlawful conduct pursuant to the NJCFA.

#### iii. Ascertainable Loss

Defendants contend Plaintiffs' Complaint must be dismissed because they have not, and cannot, establish an ascertainable loss, as required in an NJCFA pleading. (ECF No. 158-1 at 57.) An "ascertainable loss" is one that is "quantifiable or measurable." Thiedemann v. Mercedes-Benz USA, LLC, 183 N.J. 234, 872 A.2d 783, 793 (N.J. 2005). A "plaintiff must suffer a definite, certain and measurable loss, rather than one that is merely theoretical." Bosland, 964 A.2d at 749. However, New Jersey courts have found that "if the defendant or a non-party takes action to ensure that plaintiff sustains no out-of-pocket loss or loss of value prior to litigation, then plaintiff's CFA claim may fail." D'Agostino, 78 A.2d at 543; see also Thiedemann, 872 A.2d at 794 (finding no ascertainable loss when defendant repaired defect in accordance with terms of warranty). Courts support alleged damages based on either an out-of-pocket theory or a benefit of the bargain theory. See Smajlaj v. Campbell Soup Co., 782 F.Supp.2d 84, 99-103 (D.N.J. 2011). "An out-of-pocket-loss theory will suffice only if the product received was essentially worthless." Mladenov v. Wegmans Food Mkts., Inc., 124 F.Supp.3d 360, 374 (D.N.J. 2015). "A benefit-of-the-bargain theory requires that the consumer be misled into buying a product that is ultimately worth less than the product that was promised." Id. (citation omitted). Additionally, plaintiffs must set forth allegations sufficient to show that those losses are causally connected to defendant's alleged conduct. Bosland, 964 A.2d at 749.

Plaintiffs have adequately pled an ascertainable loss. Plaintiffs' Complaint fails to plead an ascertainable loss under the "out-of-pocket-loss" theory because it never alleges that the products are "essentially worthless." *Mladenov*, 124 F.Supp.3d at 374, however, Plaintiffs have adequately pled ascertainable losses pursuant to the "benefit-of-the-bargain theory." A plaintiff alleging an ascertainable loss under the benefit of the bargain theory "states a claim if he or she alleges (1) a reasonable belief about the product induced by a misrepresentation; and (2) that the difference in value between the product promised and the one received can be reasonably quantified." Smajlaj, 782 F.Supp.2d at 99. As such, a plaintiff " 'must proffer evidence of a loss that is not hypothetical or illusory' and that is 'presented with some certainty demonstrating that it is capable of calculation." Id. (quoting *Thiedemann*, 872 A.2d at 792-93); see also Hemy v. Perdue Farms, Inc., 2011 WL 6002463, at \*18 (D.N.J. Nov. 30, 2011) (holding that the allegation that plaintiff was charged a "premium," by itself, does not support a claim for an ascertainable loss).

\*16 Plaintiffs have alleged that they were misled as to the difference between the benchmark prices and the "true prices" of the medications. (ECF No. 131 ¶¶ 359-63, 379-83.) Plaintiffs contend that Defendants intentionally and knowingly misrepresented material facts and thereby "inflated" the price of analog insulin to the detriment of the consumers, who "pay for analog insulin based on the medicines' benchmark price." (ECF No. 131 ¶¶ 10, 209.) Accordingly, Plaintiffs have adequately pled an ascertainable loss pursuant to the "benefit-of-the-bargain" theory, as they contend that they were "unfairly deprived of the benefit of the bargain" as they paid more than their pro-rata share of the net prices of the subject insulin. (ECF No. 131 ¶¶ 368-70.)

As Plaintiffs have sufficiently pled unlawful conduct with specificity as well as an ascertainable loss, Defendants' Motion to Dismiss Plaintiffs' Amended Complaint is **DENIED** as to Counts Three, Four, and Five.

#### C. Plaintiffs' State Law Claims, Generally

Defendants contend that all of Plaintiffs' various state law claims should be dismissed, as Plaintiffs fail to allege fraudulent, unfair, or unconscionable conduct (ECF No. 158-2 at 4-5), all of Plaintiffs' claims are cursory recitations of the statutory elements (Id. at 5-6, 130 S.Ct. 983), all the claims fail to plead proximate causation (*Id.* at 6-7, 130 S.Ct. 983),

all the claims fail to comply with Rule 9(b) (*Id.* at 7-8, 130 S.Ct. 983), and all the claims fail because the Plaintiffs' damages are speculative (*Id.* at 8-9, 130 S.Ct. 983). This Court finds Plaintiffs have adequately alleged fraudulent, unfair, or unconscionable conduct, have pled proximate causation, and have satisfied the requirements of Rule 9(b). Additionally, Plaintiffs have also adequately pled an ascertainable loss. (ECF No. 131 ¶ 250.) Accordingly, Defendants' Motion to Dismiss Plaintiffs' Amended Complaint is **DENIED** as to Counts Six through Fifty-Nine. 11

Defendants' motion to dismiss each count herein is only denied as to the extent that such counts may be dismissed on other grounds.

#### D. Plaintiffs' State Law Claims, Specifically

#### i. Article III Standing

Defendants contend that seventeen of the various state law claims asserted against them should be dismissed as they each lack a plaintiff with Article III standing. (ECF No. 158-2 at 9-11.) Specifically, Defendants assert that the Complaint contains seventeen counts under the laws of states in which no named plaintiff resides or is alleged to have made any purchases of the subject insulin analog. 12 (ECF No. 158-2) at 10.) "Plaintiffs have the burden to establish standing." Winer Family Trust v. Queen, 503 F.3d 319, 325 (3d Cir. 2007). "[A] plaintiff who raises multiple causes of action 'must demonstrate standing for each claim he seeks to press.' " In re Schering Plough Corp. Intron/Temodar Consumer Class Action, 678 F.3d 235, 245 (3d Cir. 2012) (quoting DaimlerChrysler Corp. v. Cuno, 547 U.S. 332, 352, 126 S.Ct. 1854, 164 L.Ed.2d 589 (2006) ). The threshold standing determination may not be postponed to class certification, rather, "class representatives must meet Article III standing requirements the moment a complaint is filed." Neale v. Volvo Cars of N. Am., LLC, 794 F.3d 353, 367 (3d Cir. 2015) (citing Lewis v. Casey, 518 U.S. 343, 358, 116 S.Ct. 2174, 135 L.Ed.2d 606 (1996) ).

Those counts include: Count Seven (Alabama);
Count Eight (Alaska); Count Fourteen (Connecticut)
Count Fifteen (Delaware); Count Sixteen (Washington,
D.C.); Count Twenty (Hawaii); Count Thirty-Nine
(New Hampshire); Count Forty-Two (North Carolina);
Count Forty-Three (North Dakota); Count Forty-Five (Oklahoma); Count Forty-Eight (Rhode Island);

Count Forty-Nine (South Carolina); Count Fifty (South Dakota); Count Fifty-Five (Virginia); County Fifty-Six (Washington); Count Fifty-Seven (West Virginia); and County Fifty-Nine (Wyoming).

\*17 Consistent with *Neale*, district courts within the Third Circuit and throughout the nation have held that named plaintiffs in a class action "lack standing to bring claims on behalf of putative classes under the laws of states where no named plaintiff is located and where no named plaintiff purchased the product at issue." *In re: Niaspan Antitrust Litig.*, 2015 WL 8150588, at \*3 (E.D. Pa. Dec. 8, 2015). Indeed, the Complaint includes seventeen counts in which no named plaintiff resides in such state, nor is there any allegation of injury in such state. This runs afoul of the Supreme Court's holding in *DaimlerChrysler*, as well as the rules promulgated by courts of this Circuit.

Plaintiffs concede that the Complaint includes several counts for which it lacks a named plaintiff residing in, or claiming injury in, such state. (ECF No. 181 at 63.) Instead, Plaintiffs assert that they do not need to claim an injury in each state to maintain standing, citing the Third Circuit's decision in In re Prudential Ins. Co., 148 F.3d 283 (3d Cir. 1998). Plaintiffs' reliance on *Prudential* is inappropriate. While the court in Prudential held that "[o]nce individual standing by the class representative is met, a proper party is before the court" and there "remains no further separate class standing requirement in the constitutional sense," id. at 306-07, Prudential concerned a matter where the class included members alleging injury in all fifty states. Indeed, Prudential explicitly noted that the matter was "an appeal from the approval of the settlement of a nationwide class action lawsuit against Prudential Life Insurance company alleging deceptive sales practices affecting over 8 million claimants throughout the fifty states and the District of Columbia." Id. at 289 (emphasis added). As such, any attempt by Plaintiffs to assert that the holding in Prudential somehow undermines the Supreme Court's ruling in *DaimlerChrysler* is without merit.

Accordingly, Defendants' Motion to Dismiss Plaintiffs' Amended Complaint is **GRANTED WITHOUT PREJUDICE** as to Counts Seven, Eight, Fourteen, Fifteen, Sixteen, Twenty, Thirty-Nine, Forty-Two, Forty-Three, Forty-Five, Forty-Eight, Forty-Nine, Fifty, Fifty-Five, Fifty-Six, Fifty-Seven, and Fifty-Nine.

#### ii. Standing for Claims as to Particular Defendants

Defendants contend that Plaintiffs lack standing to pursue certain claims against certain defendants because none of them "suffered an injury alleged in a given state from that defendant's products." (ECF No. 158-2 at 11.)<sup>13</sup> Plaintiffs counter that all claims raised in the Complaint satisfy Rule 23's typicality requirement. (ECF No. 181 at 66-67.) To determine whether a plaintiff is typical of a class, courts consider the attributes of the plaintiff, the class as a whole, and the similarity between the plaintiff and the class. *Marcus v. BMW of N. Am., LLC*, 687 F.3d 583, 598 (3d Cir. 2012). The Third Circuit has explained the typicality requirement as follows:

[The analysis involves] three distinct, though related, concerns: (1) the claims of the class representative must be generally the same as those of the class in terms of both (a) the legal theory advances and (b) the factual circumstances underlying that theory; (2) the class representative must not be subject to a defense that is both inapplicable to many members of the class and likely to become a major focus of the litigation; and (3) the interests and incentives of the representative must be sufficiently aligned with those of the class.

Schering Plough, 589 F.3d at 599.

- Those counts are, as to Novo: Count Thirteen (Colorado); County Thirty (Massachusetts); Count Thirty-Five (Missouri); and Count Thirty-Eight (Nevada). As to Sanofi, the counts include: Count Twenty-Seven (Louisiana); County Twenty-Nine (Maryland); Count Thirty-Four (Mississippi); Count Forty-Seven (Pennsylvania); and Count Fifty-One (Tennessee).
- \*18 Although Plaintiffs' claims at issue may satisfy the three typicality prongs, this matter is distinguishable from Marcus in that Marcus dealt with claims regarding slightly differing products against a single defendant. Contrary to Plaintiffs' contention, Marcus did not hold that plaintiffs who did not purchase a product from a defendant may nevertheless sue that defendant based on their purchase of a different defendant's similar product. 14 Marcus, 687 F.3d at 599. Rather, this District has held that claims concerning products that a class-action plaintiff neither purchased nor used cannot stand. 15 See Lieberson v. Johnson & Johnson Consumer Cos., Inc., 865 F.Supp.2d 529, 537 (D.N.J. 2011) (holding that "[b]ecause Plaintiff has not alleged that she purchased or used two of the four ... products at issue here, Plaintiff cannot establish an injury-in-fact with regard to those products); see also Green v. Green Mountain Coffee Roasters, Inc., 279

F.R.D. 275, 280 (D.N.J. 2011) (holding that plaintiffs did not have standing to pursue claims concerning products that they "neither purchased nor used"). As Plaintiffs have asserted multiple claims absent allegations of such products being purchased or used in such jurisdictions, such claims cannot withstand this Motion to Dismiss.

- Similarly, this Court is unpersuaded by Plaintiffs' argument that *Riaubia v. Hyundai Motor Am.*, No. 16-5150, 2017 WL 3602520 (Aug. 22, 2017) supports its position. Like *Marcus*, *Riaubia* deals with "absent [class] members [who] were allegedly injured by the same non-conforming feature of different models of the same product, manufactured or distributed *by the same defendants* based on uniform representations." *Id.* at \*2 (emphasis added).
- 15 This Court notes that, while many decisions from this District have held that claims concerning products that a plaintiff has not alleged to have used nor purchased cannot stand, "[c]ourts in this district are divided on this issue." Neuss v. Rubi Rose, LLC, No. 16-2339, 2017 WL 2367056, at \*5 (D.N.J. May 31, 2017). In Neuss, this District declined to grant a defendant's motion to dismiss claims against one defendant from plaintiffs who had neither purchased nor used their product, on the basis that (1) the class-action plaintiffs had the same basis for each defect among the different products, (2) the products were closely related, and (3) all of the claims were against only two defendants. Id. Unlike in this matter, however, one of the defendants in Neuss was a subsidiary and agent of the other. Id. at \*2.

Accordingly, Defendants' Motion to Dismiss Plaintiffs' Amended Complaint is **GRANTED WITHOUT PREJUDICE** as to Counts Thirteen, Twenty-Seven, Twenty-Nine, Thirty, Thirty-Four, Thirty-Five, Thirty-Eight, Forty-Seven, and Fifty-One.

### iii. Statutory Prohibitions on Consumer Class Actions

Defendants contend that eight of the Plaintiffs' claims must be dismissed due to state law statutory prohibitions on consumer class actions in each respective state. <sup>16</sup> (ECF No. 158-2 at 13.) Defendants assert that the Supreme Court's holding in *Shady Grove Orthopedic Assocs.*, *P.A. v. Allstate Ins. Co*, 559 U.S. 393, 130 S.Ct. 1431, 176 L.Ed.2d 311 (2010) compels this Court to apply the class-action bar incorporated in state consumer protection laws. (ECF No. 158-2 at 14.) Plaintiffs argue that the Third Circuit's holding in *Knepper v. Rite Aid* 

Corp., 675 F.3d 249 (3d Cir. 2012) interprets Shady Grove to preclude applying state class-action bars in the consumer protection context. (ECF No. 181 at 68.)

16 Those eight counts are: Count Seven (Alabama); Count Eighteen (Georgia); Count Twenty-Six (Kentucky); Count Twenty-Seven (Louisiana); Count Thirty-Four (Mississippi); Count Thirty-Six (Montana); Count Forty-Nine (South Carolina); and Count Fifty-One (Tennessee).

Shady Grove held that the certification of a class-action under Rule 23 alleging violations of New York law did not violate the Rules Enabling Act, even though New York state law prohibited such a suit from proceeding as a class action. 559 U.S. at 406-09, 130 S.Ct. 1431. Knepper noted "[u]nder the plurality's view [in Shady Grove], any supposed substantive purpose underlying § 216(b) [the FLSA's provision barring opt-out classes] is irrelevant, and we need only determine whether Rule 23 'really regulates procedure,' which the Court has already concluded it does." 675 F.3d at 265. As such, any supposed, substantive purpose of a state law bar to class-actions is irrelevant, because Rule 23 "really regulates procedure." Id. Therefore, Defendants' contention lacks merit.

\*19 Accordingly, Defendants' Motion to Dismiss Plaintiffs' Amended Complaint is **DENIED** as to Counts Seven, Eighteen, Twenty-Six, Twenty-Seven, Thirty-Four, Thirty-Six, Forty-Nine, and Fifty-One. 17

17 Defendants' motion to dismiss each count herein is only denied as to the extent that such counts may be dismissed on other grounds.

#### iv. Privity

Defendants assert that six of Plaintiffs' claims must be dismissed as the consumer protection laws of such states require privity, which Plaintiffs have failed to plead. 18 (ECF No. 158-2 at 14-15.) Plaintiffs' concede that Kentucky law requires privity - thereby agreeing that their claim under Kentucky law should be dismissed – but that no other state law as alleged by Defendant requires privity to maintain a consumer fraud action. (ECF No. 181 at 69-70.)

18 Those six counts are: Count Nine (Arizona); Count Sixteen (Washington, D.C.); Count Twenty-One

(Idaho); Count Twenty-Six (Kentucky); Count Thirty (Massachusetts); and Count Fifty-Four (Vermont).

In support of its contention that privity is required under the Arizona Consumer Fraud Act, Ariz. Rev. Stat. § 14-1522, et seg. ("ACFA"), Defendants cite Sutter Home Winery, Inc. v. Vintage Selections, Ltd., 971 F.2d 401 (9th Cir. 1992). The court in Sutter held that the ACFA has a "clear intent to protect unwary buyers from unscrupulous sellers" and that where a plaintiff is "not a buyer, nor [a] ... target of deceptive advertising" it cannot maintain an action under the ACFA. Id. at 407. Plaintiffs have asserted that they are both "buyers," although not directly from Defendants, and the target of deceptive pricing. As Arizona jurisprudence does not explicitly require direct privity of contract between the plaintiff and defendant to maintain a suit under the ACFA, Plaintiffs' Arizona state law claim survives.

In support of its contention that privity is required under the Idaho Consumer Protection Act, I.C. § 48-601, et seg. ("ICPA"), Defendants cite Taylor v. McNichols, 149 Idaho 826, 243 P.3d 642 (Idaho 2010). Taylor held that in order to have standing under the ICPA, "the aggrieved party must have been in a contractual relationship with the party alleged to have acted unfairly or deceptively." Id. at 662; see also Haskin v. Glass, 102 Idaho 785, 640 P.2d 1186, 1189 (Idaho Ct. App. 1982) (holding "that a claim under the ICPA must be based upon a contract"). However, while a contractual relationship is necessary, courts have not determined whether direct privity is required to confer standing under the ICPA. See In re Chrysler-Dodge-Jeep Ecodiesel Mktg., Sales Practices, & Prods. Liab. Litig., 295 F.Supp.3d 927, 1021-22 (N.D. Cal. 2018) (holding that "[a]rguably, [the ICPA] and Haskin simply reflect that a plaintiff's claim must ultimately be founded on a contract; they do not necessarily require that the contract must be one entered into by the plaintiff and defendant directly"); see also Johnson v. Ford Motor Co., 2015 WL 7571841, at \*10 (S.D. W.Va. Nov. 24, 2015) (rejecting the assertion that an automobile purchaser could not sue Ford Motor Company under the ICPA because she was not a direct purchaser). Accordingly, as direct privity is not required under Idaho law, Plaintiffs' failure to plead such is not fatal to its action.

\*20 Finally, Defendants assert that the Vermont Consumer Fraud Act, Vt. Stat. Ann. Tit. 9, § 2451, et seq. ("VCFA") requires privity of contract. (ECF No. 158-2 at 15.) In support of this contention, Defendants cite Otis-Wisher v. Medtronic, Inc., 616 F. App'x 433, 435 (2d Cir. 2015), which upheld the dismissal of a claim under the VCFA finding that the plaintiff

was not a "consumer" because she was merely prescribed the device by her doctor. *Otis-Wisher* is inapplicable to this matter, as Plaintiffs undoubtedly qualify as consumers. On the contrary, in *Elkins v. Microsoft Corp.*, 174 Vt. 328, 817 A.2d 9, 20 (Vt. 2002), the Vermont Supreme Court held that "consumers can generally sue under [the VCFA] even though they are indirect purchasers of a good or service from the defendant." Thus, direct privity of contract is not required under Vermont law and Plaintiffs may assert its claim under the VCFA.

Accordingly, Defendants' Motion to Dismiss Plaintiffs' Amended Complaint is **GRANTED WITHOUT PREJUDICE** as to Count Twenty-Six and **DENIED** as to Counts Nine, Twenty-One, and Twenty-Four.<sup>19</sup>

This Court did not provide an analysis for its decision to grant Defendants' motion to dismiss Count Twenty-Six, pleading a violation of the Kentucky Consumer Protection Act, as Plaintiff conceded that such Act requires direct privity of contract, which its Complaint failed to allege. (ECF No. 181 at 69.) Additionally, this Court also did not provide an analysis of Defendants' privity of contract argument as to Count Sixteen, alleging a violation of the Washington D.C. Consumer Protection Procedures Act, or Count Thirty, alleging a violation of the Massachusetts General Law Chapter 93(A), as both counts were previously dismissed without prejudice for lack of standing.

#### v. Reliance

Defendants assert that six of Plaintiffs' claims must be dismissed as Plaintiffs failed to adequately plead reliance. (ECF No. 158-2 at 15-16.) These six counts all allege violations of state consumer fraud laws in which reliance is a necessary element. On the contrary to Defendants' contention, Plaintiffs adequately pled reliance upon Defendants' alleged misrepresentations, as well as proximate causation to their damages stemming therefrom. (ECF No. 131 ¶ 3, 206, 259, 335.) Accordingly, Defendants' Motion to Dismiss Plaintiffs' Amended Complaint is **DENIED** as to Counts Ten, Twelve, Eighteen, Thirty-One, Thirty-Eight, and Forty-Seven. 21

Those six counts are: Count Ten (Arkansas); Count Twelve (California); Count Eighteen (Georgia); Count

- Thirty-One (Michigan); Count Thirty-Eight (Nevada); and Count Forty-Seven (Pennsylvania).
- Defendants' motion to dismiss each count herein is only denied as to the extent that such counts may be dismissed on other grounds.

#### vi. Allegations of Wrongdoing

Defendants assert that five of Plaintiffs' claims must be dismissed as Plaintiffs failed to adequately plead wrongdoing within the state, as required by each respective state consumer fraud law. (ECF No. 158-2 at 16-17.) Plaintiffs contend that Defendants argument is erroneous, as each claim concerns consumers who reside in and purchased insulin in the particular state whose laws they invoke. (ECF No. 181 at 73.) The Court agrees with Plaintiffs.

Those five counts are: Count Twenty-Two (Illinois); Count Thirty-Nine (New Hampshire); Count Forty-One (New York); Count Fifty-One (Tennessee); and Count Fifty-Eight (Wisconsin).

The Illinois Consumer Fraud and Deceptive Practices Act, 815 Ill. Comp. Stat. § 505, et seq. ("ICFA") "applies only to fraudulent transactions that take place 'primarily and substantially' inside Illinois." Barbara's Sales, Inc. v. Intel Corp., 227 Ill.2d 45, 316 Ill.Dec. 522, 879 N.E.2d 910, 921 (Ill. 2007) (quoting Avery v. State Farm Mut. Auto Ins. Co., 216 Ill.2d 100, 296 Ill.Dec. 448, 835 N.E.2d 801, 852 (Ill. 2005) ). It is evident that the purchase of insulin by a plaintiff within Illinois would satisfy this requirement, and Plaintiffs' Complaint pled such. Therefore, Plaintiffs adequately pled wrongdoing under Illinois law.

\*21 The New Hampshire Consumer Protection Act, N.H. Rev. Stat. § 358-A:1, et seq. ("NHCPA") is construed "to cover a defendant's extra-territorial acts if those acts affect travel or commerce within the state." Harbour Capital Corp. v. Allied Capital Corp., 2009 WL 2185449, at \*8-9 (D.N.H. July 22, 2009). Defendants may not "injure trade or commerce in New Hampshire but escape liability under [the NHCPA] by remaining outside the state." Id. As Plaintiffs have pled extra-territorial acts affecting commerce within New Hampshire, they have sufficiently pled wrongdoing under New Hampshire law.

New York courts hold that in order to allege injury under the New York General Business Law §§ 349-350, the plaintiff must allege that "the transaction in which the consumer is

deceived" occurred in New York. Goshen v. Mut. Life Ins. Co. of New York, 98 N.Y.2d 314, 746 N.Y.S.2d 858, 774 N.E.2d 1190, 1195 (N.Y. 2002). In Goshen, the plaintiff "purchased his policy and paid his premiums in Florida, through a Florida insurance agent," and the Court found that "for the purposes of section 349, any deception took place in Florida, not in New York." Id. at 1196, 746 N.Y.S.2d 858, 774 N.E.2d. On the contrary, Plaintiffs allege that the New York class members purchased the insulin analog in New York, and thus that the deception occurred in New York. Accordingly, Plaintiffs have adequately alleged wrongdoing in New York.

Finally, this Court is satisfied that Plaintiffs have adequately pled wrongdoing in both Tennessee and Wisconsin so as to withstand Defendants' Motion to Dismiss. The Tennessee Consumer Protection Act, Tenn. Code Ann. § 47-18-101, et seq. ("TCPA") is to "be liberally construed" to "protect consumers and legitimate business enterprises from those who engage in unfair or deceptive acts or practices in the conduct of any trade or commerce in part or wholly within the state." Id. at § 47-18-102(2). Tennessee courts allow plaintiffs discovery "in order to tie its TCPA claims to specific transactions occurring in Tennessee." Encore Med., L.P. v. Jay Kennedy, D.C., 2013 WL 839838, at \*32 (W.D. Pa. Mar. 6, 2013). Similarly, the Wisconsin Supreme Court has held that the purpose of the Wisconsin Deceptive Trade Practices Act. Wis. Stat. § 110.18 ("DTPA") "includes protecting Wisconsin residents from untrue, deceptive, or misleading representation made to induce action." K&S Tool & Die Corp. v. Perfection Mach. Sales, Inc., 301 Wis.2d 109, 732 N.W.2d 792, 802 (Wis. 2007). This necessarily includes transactions that took place in Wisconsin, see, e.g., In re GM LLC Ignition Switch Litig., 257 F.Supp.3d 372, 446-60 (S.D.N.Y. 2017), which the Complaint pleads. As such, Plaintiffs have sufficiently pled factual allegations asserting wrongdoing in Tennessee and Wisconsin so as to withstand Defendants' Motion to Dismiss.

Accordingly, Defendants' Motion to Dismiss Plaintiffs' Amended Complaint is **DENIED** as to Counts Twenty-Two, Thirty-Nine, Forty-One, and Fifty-One.

#### vii. Procedural Requirements

Finally, Defendants contend that Plaintiffs' claims under Mississippi law, Count Thirty-Four, and Ohio law, Count Forty-Four, must be dismissed because they fail to meet procedural requirements under respective state laws. (ECF No. 158-2 at 17-18.) As this Court has determined that Plaintiffs lack standing to bring its Mississippi state claim, Count Thirty-Four will not be analyzed again herein.

Defendants assert that this Court must dismiss Plaintiffs' claim pursuant to the Ohio Consumer Sales Practice Act, Ohio Rev. Code Ann. § 1345.01, et seq. ("OCSPA") because the statute's section on remedies prohibits a plaintiff from bringing a class action "unless the defendant has notice that conduct substantially similar to its alleged conduct is deceptive or unconscionable as declared by either (1) a rule adopted by the Ohio Attorney General, or (2) an Ohio state court holding." Chapman v. Tristar Prods., Inc., 2016 WL 6216135, at \*4 (N.D. Ohio Oct. 25, 2016). "Ohio courts are to construe the OCSPA liberally in favor of consumers." Id. Courts interpreting Ohio law have held that the notice argument "is not appropriate at the moment-todismiss stage; it belongs at the class certification or summary judgment stages." Id. at 4, 130 S.Ct. 983 (citing In re Whirlpool Corp. Front-Loading Washer Prod. Liab. Litig., 684 F.Supp.2d 942, 948 (N.D. Ohio 2009). As such, there are no grounds to dismiss Plaintiffs' claims at Ohio law at this juncture. Accordingly, Defendants' Motion to Dismiss Plaintiffs' Amended Complaint is **DENIED** as to Count Forty-Four.

#### IV. Conclusion

\*22 For the reasons set forth above, Defendants' Motion to Dismiss is **GRANTED IN PART** and **DENIED IN PART** as set forth herein and in the accompanying order.

#### **All Citations**

Not Reported in Fed. Supp., 2019 WL 643709, RICO Bus.Disp.Guide 13,138

**End of Document** 

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Document 1451-1 PageID: 33196

## Tab 14

2020 WL 759573 Only the Westlaw citation is currently available. United States District Court, D. New Jersey.

Re: IRENE, et al.,
v.
MICHAEL WHALEY
INTERIORS, INC., et al.

Civil Action No. 19-14998 (ES) (ESK) | Signed February 13, 2020

#### **Attorneys and Law Firms**

Jason A. Meisner, Jonathan F. Donath, Coughlin Duffy LLP, Morristown, NJ, for Larry Irene, Alison Irene.

Patrick B. Minter, Donnelly Minter & Kelly, Morristown, NJ, for Michael Whaley Interiors, Inc, Michael Whaley.

#### **LETTER OPINION AND ORDER**

Esther Salas, U.S.D.J.

#### \*1 Dear counsel:

Pending before the Court is defendants Michael Whaley Interiors, Inc. ("Whaley Interiors") and Michael Whaley's (collectively, "Defendants") motion to dismiss plaintiffs Larry Irene and Alison Irene's (collectively, "Plaintiffs") Amended Complaint under Federal Rule of Civil Procedure 12(b)(6). (D.E. Nos. 6 & 6-1 ("Def Mov. Br.")). Having considered the parties' submissions, the Court decides this matter without oral argument. *See* Fed. R. Civ. P. 78(b); L. Civ. R. 78.1(b). As set forth below, the Court GRANTS Defendants' motion.

Plaintiffs allege that Michael Whaley, as the sole shareholder of Whaley Interiors, controls the operations, decision making, and finances of Whaley Interiors. (D.E. No. 2 ("Amended Complaint" or "Am. Compl.") ¶ 27–28).

Plaintiffs allege that on or about September 30, 2013, they engaged Defendants "to provide certain interior design services to Plaintiffs including but not limited to Design Concept Services, Specification and Purchasing Services as well as additional, related services." (Am. Compl. ¶

- 9). Plaintiffs further allege that the services Defendants ultimately provided were not in accordance with their obligations under the relevant agreement in several respects, and that Defendants made a number of misrepresentations to Plaintiffs about their services. (Id. ¶¶ 17–32). Ultimately, Plaintiffs allege that they "paid more than \$1,200,000.00 for these purported interior design services." (Id. ¶ 16). Plaintiffs now seek a variety of damages against Defendants for (i) breach of contract; (ii) breach of the covenant of good faith and fair dealing; (iii) misrepresentation/common law fraud; and (iv) violation of the New Jersey Consumer Fraud Act ("NJCFA").<sup>2</sup>
- In their opposition brief, Plaintiffs clarify that the only claims that are brought against Michael Whaley individually are the misrepresentation/fraud claim and NJCFA claim. (D.E. No. 12 ("Pl. Opp. Br.") at 6).

Defendants move to dismiss the Amended Complaint, generally arguing that Plaintiffs (i) fail to provide sufficient factual support for each of their claims, (ii) plead claims that are impermissibly duplicative of one another, and (iii) with respect to the fraud claims, fail to plead sufficient facts under the heightened pleading requirement. (See generally Def. Mov. Br.). In response, Plaintiffs argue that they adequately plead their claims under either the regular or heightened pleading standard for fraud, and that their allegedly duplicative claims are based on different facts or are pled in the alternative. (See generally Pl. Opp. Br.). Additionally, Plaintiffs ask that the Court permit an amendment of the Amended Complaint if dismissal is granted.

As a preliminary matter, Plaintiffs use their opposition brief to provide the Court with "a number of additional facts which may be included in ... an amendment." (Id. at 3-4). Plaintiffs describe—in more detail than alleged in the Amended Complaint—how they believe Defendants' services fell below what was promised in the governing contract and/or through Defendants' representations. For example, Plaintiffs explain that (i) some items provided by Defendants were broken on arrival; (ii) some items wore out within mere months; (iii) some furniture items proved to be inappropriate for outdoor use, contrary to representations by Defendants; and (iv) Defendants failed to design Plaintiffs' home in a way that was suitable for children, despite their representation that their work would be performed with a "combination of talent and practical knowledge." (Id.). Based on Plaintiffs' admission that they have more facts relevant to their claims and in the interest of efficiency, the Court

is inclined to terminate the motion to dismiss to allow Plaintiffs to amend the operative complaint to include these and any other facts relevant to their claims before it considers dismissal.<sup>3</sup> Nevertheless, because the Court also shares some of the same concerns raised by Defendants in their motion to dismiss, the Court addresses them.

- 3 "It is axiomatic that the complaint may not be amended by the briefs in opposition to a motion to dismiss." *Com. of Pa. ex rel. Zimmerman v. PepsiCo., Inc.*, 836 F.2d 173, 181 (3d Cir. 1988) (alteration omitted). As such, the Court makes no determination as to the *sufficiency* of the additional allegations in this Opinion. *See Baldeo v. City of Paterson*, No. 18-5359, 2019 WL 277600, at \*11 (D.N.J. Jan. 18, 2019) (explaining that the Court will not "opine on a theory that has not been pled in the [Amended] Complaint").
- \*2 Legal Standards: Federal Rule of Civil Procedure 8(a) (2) requires a complaint contain a "short and plain statement of the claim showing that the pleader is entitled to relief." But, to survive a motion to dismiss pursuant to Federal Rule of Civil Procedure 12(b)(6), the complaint must contain "enough facts to state a claim to relief that is plausible on its face." Bell Atl. Corp. v. Twombly, 550 U.S. 544, 570 (2007). "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009) (quoting Twombly, 550 U.S. at 556). A complaint cannot suffice "if it tenders [only] 'naked assertion[s]' devoid of 'further factual enhancement,' " because while Rule 8 "does not require 'detailed factual allegations,' ... it demands more than an unadorned, the-defendant-unlawfully-harmedme accusation." Id. (quoting Twombly, 550 U.S. at 555 & 557). The Court is "required to accept as true all allegations in the complaint and all reasonable inferences that can be drawn from them after construing them in the light most favorable to the nonmovant." See, e.g., McDermott v. Clondalkin Grp., Inc., 649 F. App'x 263, 266 (3d Cir. 2016).

Breach of the Agreement (Count I): Defendants argue that Plaintiffs do not adequately allege a breach of contract claim because the Amended Complaint fails to allege a single portion of the agreement that Defendants violated. (Def. Mov. Br. at 7–9). Although Plaintiffs do provide some general allegations about what the agreement required and what the Defendants "failed to" do, Plaintiffs do not adequately tie those allegations to specific provisions of the governing contract. See Grande Village LLC v. CIBC Inc., No. 14-3495,

2015 WL 1004236, at \*5 (D.N.J. Mar. 6, 2015) (explaining that a breach of contract claim must "identify what contractual provision was breached"). Additionally, even if the Court were to infer which portions of the agreement were allegedly violated, Plaintiffs' allegations as to *how* the Defendants breached the agreement are scarce, and the Court is unable to "draw the reasonable inference that the defendant is liable for the misconduct alleged." *Iqbal*, 556 U.S. at 662; *see also Frederico v. Home Depot*, 507 F.3d 188, 204 (3d Cir. 2007). Count I is thus dismissed, *without prejudice*.

By comparing the Amended Complaint to the agreement, the Court can infer at least some provisions that were allegedly breached, but others are not so clear. Additionally, because Plaintiffs seem to argue that at least some of their claims are based on language that is "subsumed" in the contract or "implied in fact" (Pl. Opp. Br. at 9–10), the Court cannot adequately determine where Plaintiffs are alleging a breach of the agreement itself.

Breach of the Covenant of Good Faith and Fair Dealing (Count II): Defendants argue that Plaintiffs' claim for breach of the covenant of good faith and fair dealing cannot survive because it is entirely duplicative of the breach of contract claims. (Def. Mov. Br. at 9-10). In response, Plaintiffs argue that their claims are permissibly pled in the alternative. (Pl. Opp. Br. at 10-11). The Court agrees with Defendants that the Amended Complaint, as currently drafted, expressly bases this claim on the same conduct that forms the basis of the contract claim: "Defendants breached the covenant of good faith and fair dealing by failing to satisfy their obligations under the Agreement and otherwise." (Am. Compl. ¶ 41). And under New Jersey law, "[a] breach of the covenant of good faith and fair dealing must not arise out of the same conduct underlying an alleged breach of contract action." TBI Unlimited, LLC v. Clear Cut Lawn Decisions, LLC, No. 12-3355, 2013 WL 6048720, at \*3 (D.N.J. Nov. 14, 2013) (citing Wade v. Kessler Inst., 798 A.2d 1251, 1259-60 (N.J. 2002)). But the Court also recognizes that "pleading in the alternative is permissible in New Jersey, so long as the alternative claims meet the pleading standards." In re AZEK Bldg. Prod., Inc., Mktg. & Sales Practices Litig., 82 F. Supp. 3d 608, 620 (D.N.J. 2015). Thus, although Plaintiff may be able to plead duplicative claims in the alternative, <sup>5</sup> the Court finds that the breach of the covenant of good faith and fair dealing claim is insufficiently pled for the same reasons the breach of contract claim is insufficiently pled. As such Count II is also dismissed, without prejudice.

The Court notes that courts in this district do not always permit alternative pleading of claims for breach of contract and breach of the covenant of good faith and fair dealing, especially where the claims are identical.

Lewis v. Gov't Employees Ins. Co., No. 18-5111, 2019

WL 1198910, at \*3 (D.N.J. Mar. 14, 2019). But because neither claim is adequately pled here, the Court does not have sufficient information to dismiss the claims as duplicative at this time. The Court may revisit this issue as it pertains to any second amended complaint.

\*3 Fraud Claims (Counts III, IV, and V): Defendants argue that Plaintiffs' fraud-based claims should be dismissed for failure to comply with the heightened pleading requirement of Federal Rule of Civil Procedure 9(b). (Def. Mov. Br. at 12–14). Rule 9(b) requires a party alleging fraud or mistake to "state with particularity the circumstances constituting fraud or mistake." Fed. R. Civ. P. 9(b). A plaintiff may satisfy Rule 9(b) by pleading the date, place or time of the fraud, or through alternative means of "injecting precision and some measure of substantiation into the[ ] allegations of fraud." Seville Indus. Mach. Corp. v. Southmost Mach. Corp., 742 F.2d 786, 791 (3d Cir. 1984). In sum, the Third Circuit has advised that, "at a minimum," a plaintiff must support allegations of fraud "with all of the essential factual background that would accompany the first paragraph of any newspaper story—that is, the who, what, when, where and how of the events at issue." In re Rockefeller Ctr. Prop. Inc. Sec. Litig., 311 F.3d 198, 217 (3d Cir. 2002) (internal quotation marks omitted). Plaintiffs' conclusory statements that defendant Michael Whaley made various representations or misrepresentations to them, without more, are plainly insufficient. (See Am. Compl. ¶¶ 15, 30–32, 45–46 (pg. 7) $^6$  & 45 (pg. 8)). Accordingly, Counts III, IV, and V are dismissed, without prejudice, for failure to state a claim.

- The Court uses page numbers since certain paragraphs numbers were repeated in the Amended Complaint.
- 7 Defendants also argue that Plaintiffs' misrepresentation/ common law fraud claim is barred by the economic

loss doctrine, which prohibits a plaintiff from recovering in tort economic losses to which their entitlement only flows from a contract. (Def. Mov. Br. at 11–12). But because Plaintiffs' fraud allegations are insufficiently pled, the Court cannot make a determination as to whether this claim should be barred by the doctrine of economic loss.

Leave to Amend: Plaintiffs request leave to amend the Amended Complaint (Pl. Opp. Br. at 14–16), and Defendants oppose this request, arguing that any amendment would be futile (D.E. No. 13 at 7). Federal Rule of Civil Procedure 15(a)(2) provides that the Court "should freely give leave [to amend a pleading] when justice so requires." However, no amendment should be permitted if an amendment would be futile. See Harrison Beverage Co. v. Dribeck Imp., Inc., 133 F.R.D. 463, 468 (D.N.J. 1990). The Court is not convinced that amendment would be futile, and thus Plaintiffs are granted leave to file a second amended complaint.

Accordingly, IT IS on this 13th day of February 2020,

**ORDERED** that Defendants' motion to dismiss is GRANTED; the Amended Complaint is dismissed *without prejudice*; and it is further

**ORDERED** that Plaintiffs are granted leave to amend; Plaintiffs have thirty days from the date of entry of this Order to file a second amended complaint addressing the deficiencies discussed in this Letter Opinion and Order, and failure to do so may result in dismissal of any or all claims with prejudice; and it is further

**ORDERED** that the Clerk of Court shall terminate Docket Entry Number 6.

#### **All Citations**

Slip Copy, 2020 WL 759573

**End of Document** 

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## **Tab 15**

2011 WL 198026
Only the Westlaw citation is currently available.
NOT FOR PUBLICATION
United States District Court, D. New Jersey.

Tenisha JAMES, individually and on behalf of all others similarly situated, Plaintiffs,

v.

JOHNSON & JOHNSON CONSUMER COMPANIES, INC., Defendants.

Civil No. 10-cv-03049 (DMC)(JAD). | | Jan. 20, 2011.

#### Attorneys and Law Firms

Scott M. Lempert, Sandals & Associates, P.C., Philadelphia, PA, for Plaintiff.

Daniel B. Carroll, Drinker, Biddle & Reath, LLP, Florham Park, NJ, for Defendant.

#### **OPINION**

DENNIS M. CAVANAUGH, District Judge.

\*1 This matter comes before the Court upon motion by Johnson & Johnson Consumer Companies, Inc. ("Defendant") to dismiss the Plaintiff's Consolidated Amended Class Action Complaint ("CACAC") pursuant to Fed.R.Civ.P. 12(b)(1) for lack of subject matter jurisdiction. Pursuant to Fed. R. Civ. Pro 78, no oral argument was heard. After considering the submissions of the parties, and based upon the following, Defendants motion is granted.

#### I. BACKGROUND

The ten plaintiffs joined in this Complaint allege that Defendant J & J violated the FDA's ban on methylene chloride as an ingredient in cosmetic products, pursuant to 21 C.F.R. § 700.19. Attorney for Plaintiffs previously brought six virtually identical cases before this Court, four of which were dismissed on August 2, 2010 for lack of standing pursuant to a motion for reconsideration filed by Defendant Johnson & Johnson. The CACAC allegedly raises new factual and legal issues that distinguish this Complaint from the others

that were dismissed by this Court, including allegations that Johnson & Johnson has been investigated by the FDA, and that methyl chloride is an ingredient in its baby shampoo.

Vercellono v. Gerber Products Co. et al., Case 2:09-cv-02905 DMC-MF, CLOSED 8/2/10; Crouch v. Johnson and Johnson Consumer Cos., Inc. et al., Case 2:09-cv-02905 DMC-MF, CLOSED 8/2/10; Levinson v. Johnson & Johnson Consumer Cos., Inc. et al., Case 2:09-cv-03317 DMC-MF, CLOSED 8/2/10; Boyd v. Johnson & Johnson Consumer Cos. Inc., Case 2:09-cv-03135 DMC-MF; CLOSED 8/2/10.

#### II. LEGAL STANDARD

As the Supreme Court has long held, "Constitutional standing requires (1) injury-in-fact, which is an invasion of a legally protected interest that is (a) concrete and particularized, and (b) actual or imminent, not conjectural or hypothetical; (2) a causal connection between the injury and the conduct complained of; and (3) it must be likely, as opposed to merely speculative, that the injury will be redressed by a favorable decision. Lujan v. Defenders of Wildlife, 504 U.S. 555, 560-61, 112 S.Ct. 2130, 119 L.Ed.2d 351 (1992). Moreover, a "legally and judicially cognizable" injury-in-fact must be "distinct and palpable," not "abstract or conjectural or hypothetical." Raines v. Byrd, 521 U.S. 811, 819, 117 S.Ct. 2312, 138 L.Ed.2d 849 (1997); Allen v. Wright, 468 U.S. 737, 751, 104 S.Ct. 3315, 82 L.Ed.2d 556 (1984) (internal quotations omitted) (quoting Warth v. Seldin, 422 U.S. 490, 498, 95 S.Ct. 2197, 45 L.Ed.2d 343 (1975), and Los Angeles v. Lyons, 461 U.S. 95, 101-02, 103 S.Ct. 1660, 75 L.Ed.2d 675 (1983)). As the Third Circuit has held, "while it is difficult to reduce injury-in-fact to a simple formula, economic injury is one of its paradigmatic forms." See Danvers Motor Co., Inc. v. Ford Motor Co. 432 F.3d 286, 291 (C.A.3 (N.J.),2005).

"There is a fundamental difference of review under Fed.R.Civ.P. 12(b)(1), where the existence of disputed facts will not preclude the Court from evaluating the merits of the jurisdictional claim, and Fed.R.Civ.P. 12(b)(6) where the Court is required to accept as true all the allegations of the complaint and all inferences arising from them." *Anjelino v. New York*, 200 F.3d 73, 87 (Dd Cir., 1999). "[T]he threshold to withstand a motion to dismiss under [Rule] 12(b)(1) is thus lower than that required to withstand a Rule 12(b)(6) motion." *Kehr Packages, Inc. V. Fidelcor, Inc.*, 926 F.2d 1406, 1409 (3d Cir., 1991).

#### III. DISCUSSION

\*2 The Court accepts Plaintiff's contention that economic injury is sufficient to confer Article III standing such that the Court has subject matter jurisdiction over this case. The Court notes the language of Danvers Motor Co., Inc. v. Ford Motor Co. 432 F.3d 286, 293 (C.A.3 (N.J.), 2005) in which the Third Circuit held that "monetary harm is a classic form of injury-infact," and that "injury-in-fact is not Mount Everest." In spite of that language, however, Plaintiffs cannot clear the threshold requirement for showing economic injury. As the Court understands the CACAC, the economic injury for which Plaintiffs seeks redress is the price Plaintiffs paid for shampoo, which they then apparently used in bathing their children, without adverse health reactions. Whatever injury they claim to have suffered due to their subsequent discovery of methyl chloride in the shampoo could not, therefore, have been economic.<sup>2</sup> Simply put, Plaintiffs bought and used shampoo, and subsequently wished that they had not done so because they feared for the future safety of their children. Their assertion that because the product was tainted, the injury occurred at the moment of purchase, is unavailing. Plaintiff's reasoning in the CACAC is circular and unpersuasive as to the contention that Plaintiffs suffered an injury-in-fact. The CACAC avers that "had Plaintiffs known the true nature of Defendant's baby shampoo, they neither would have purchased it nor allowed their children to be exposed to it." This is undoubtedly correct, but the conclusion that "consequently, Plaintiffs have been economically damaged" simply does not follow. (See ECF Doc. 27, page ID# 483). Presumably, had Plaintiffs known about the alleged toxicity of the shampoo prior to using the product they would either have returned it unopened, or not purchased it in the first place. Once the product had been consumed, however, there was no economic injury for Plaintiffs to complain of, and the fear of future injury is legally insufficient to confer standing. Plaintiffs received the benefit of their bargain so long as there were no adverse health consequences, and the product worked as intended, meaning that the hair of Plaintiff's children was cleansed, and their eyes and skin were not irritated. There is nothing in the CACAC to suggest otherwise. The Court finds that the facts as pled in the CACAC are legally

insufficient to demonstrate an injury-in-fact of even the most de minimis amount, and that no further restyling of the CACAC could overcome this jurisdictional hurdle. It would be both foolish and impossible to parse and measure the amount of shampoo each Plaintiff used prior to the discovery of taint, and the Court will not entertain such a fractionated analysis. Short of seeking redress for the unused portion of a bottle of shampoo that was discarded subsequent to discovery of the alleged contamination, a practical and legal absurdity, there is simply no cognizable economic injury. The Court need not reach the issue on which the previous four cases were dismissed, namely the contention that methyl chloride was not an "ingredient" as that term is understood by the Food and Drug Administration, although the Court notes that Plaintiff's syllogistic reasoning, that methyl chloride was a "component," and therefore an "ingredient" is neither a factual nor a legal improvement over Plaintiff's previous allegations. To the extent that there is no injury-in-fact, either economic or otherwise, the "per se" adulteration of the product is simply irrelevant to these Plaintiffs, since they have no standing to bring the claim before this Court. Plaintiff should consider this issue to have been fully litigated and thus precluded for future consideration by the Court.

It should be noted that Plaintiffs have not alleged economic injury on a theory that they paid a premium price for this brand of shampoo based on Johnson & Johnson's misrepresentation of their product as being safe and non-toxic for children, more so than comparable but less expensive alternatives. *See Desiano v. Warner–Lambert Co.*, 326 F.3d 339 (2d Cir., 2003).

#### III. CONCLUSION

\*3 For the reasons contained herein, Defendant's motion to dismiss pursuant to Fed.R.Civ.P. 12(b)(1) is **granted** An appropriate order follows this opinion.

#### **All Citations**

Not Reported in F.Supp.2d, 2011 WL 198026

**End of Document** 

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## **Tab 16**

KeyCite Yellow Flag - Negative Treatment
Declined to Follow by Gregorio v. Ford Motor Company, E.D.Mich., March
1, 2021

#### 2010 WL 11579013

Only the Westlaw citation is currently available.
United States District Court, E.D. North Carolina,
Southern Division.

Earl Clyde KELLY, on behalf of himself and all others similarly situated, Plaintiffs,

V.

GEORGIA-PACIFIC LLC, and Georgia Pacific Wood Products LLC, Defendants.

No. 7:08-CV-197-D | Signed 08/31/2010

#### Attorneys and Law Firms

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Leah A. Epstein, Joshua D. Jewkes, Robert B. Remar, Rogers & Hardin LLP, Atlanta, GA, Martin L. White, Robert L. Burchette, Johnston, Allison & Hord, P.A., Charlotte, NC, for Defendants.

#### **ORDER**

#### JAMES C. DEVER III, United States District Judge

\*1 On September 30, 2009, the court dismissed certain claims and allowed plaintiff Clyde Earl Kelly ("Kelly" or "plaintiff") to amend his complaint. See Kelly v. Georgia Pacific LLC, 671 F. Supp. 2d 785 (E.D.N.C. 2009). Kelly has since filed a first amended complaint [D.E. 40] and a second amended complaint [D.E. 69]. In the second amended complaint, Kelly and two plaintiff intervenors James and Teresa Wicker (collectively "plaintiffs") bring several North Carolina state-law claims against Georgia-Pacific LLC and Georgia Pacific Wood Products LLC (collectively "defendants" or "GP"). Defendants are the

designers and manufacturers of PrimeTrim, a product used in building plaintiffs' homes. Plaintiffs contend that PrimeTrim failed to work as promised, that their remedies under PrimeTrim's express warranty are not adequate, and that they should be able to pursue this case as a class action. Defendants continue to acknowledge the viability of plaintiffs' expresswarranty claim, but move to dismiss the remaining state-law claims for failure to state a claim upon which relief can be granted. As explained below, the court grants defendants' partial motion to dismiss the second amended complaint.

I.

Georgia Pacific LLC and Georgia Pacific Wood Products LLC are designers and manufacturers of exterior building products, including PrimeTrim. See Sec. Am. Compl. ¶ 18; Answer ¶ 18. GP sold PrimeTrim—directly and through dealers and other retail outlets—within the United States (including in North Carolina), to homeowners, developers, contractors, and subcontractors. Sec. Am. Compl. ¶ 16; see Answer ¶¶ 16, 18.

Homebuilders use PrimeTrim on the exterior of homes as fascia, soffit, corner board, window trim, and door trim. Sec. Am. Compl. ¶ 1; Answer ¶ 1. GP marketed, advertised, and warranted that PrimeTrim was fit for the ordinary purpose for which wood trim is used, free from defects, suitable for exterior use, reliable, and superior to wood. Sec. Am. Compl. ¶¶ 30, 31; see Answer ¶¶ 30, 31. Specifically, GP warranted that "PrimeTrim may be installed wherever non-structural wood trim can be used." Sec. Am. Compl. ¶ 30; see Answer ¶ 30.

Kelly is a resident of New Hanover County, North Carolina and, since late 2003, has resided in a home that he built in Carolina Beach, North Carolina. Sec. Am. Compl. ¶ 5. Kelly's builder used PrimeTrim in building plaintiff's home. See id. ¶ 112; Answer ¶ 112. However, Kelly did not directly purchase PrimeTrim from GP. See id. ¶ 112. According to defendants, Kelly's builder, Walter Thorpe McCartney, installed the PrimeTrim in plaintiff's home. Third-Party Compl. ¶ 13. After installation, moisture penetrated behind the PrimeTrim, and the moisture absorption caused damage to the PrimeTrim and to "any material to which PrimeTrim is attached" in the home. Sec. Am. Compl. ¶ 35; see id. ¶¶ 55–69.

The Wickers are residents of New Hanover County, North Carolina and, since July 2004, have resided in a home that

they built in Wilmington, North Carolina. Sec. Am. Compl. ¶ 6. The Wickers' builder used PrimeTrim in building their home. See id. ¶ 43; Sec. Third-Party Compl. ¶ 4. The Wickers did not directly purchase PrimeTrim from GP. See Sec. Third-Party Compl. ¶ 17. According to defendants, the Wickers' builder, Donaldson Construction & Management, Inc. ("Donaldson Construction"), installed the PrimeTrim in the Wickers' home. Id. After installation, moisture penetrated behind the PrimeTrim, and the moisture absorption caused damage to the PrimeTrim and to "any material to which PrimeTrim is attached" in the home. Sec. Am. Compl. ¶ 35.

\*2 According to the second amended complaint, GP failed to disclose that PrimeTrim would degrade and fail when used for its intended purpose. See Sec. Am. Compl. ¶ 34. Plaintiffs attribute these failures to design defects. Id. Plaintiffs also contend that GP did not adequately instruct plaintiffs and other direct and indirect purchasers on how to properly install PrimeTrim. Id. ¶ 47. Plaintiffs cite as an example that the instructions did not include steps to seal and to prime any site-cut ends of the PrimeTrim boards despite GP knowing that builders would cut the boards on site. Id. As a result, when builders cut the PrimeTrim on site before installing it and did not seal or prime the site-cut boards, the PrimeTrim became vulnerable to moisture intrusion. Id. Accordingly, when builders followed GP's instructions for installing PrimeTrim, PrimeTrim permitted water intrusion, which damaged the PrimeTrim and the structures in which it was installed. Id. ¶¶ 50-52.

PrimeTrim is covered by a thirty-year limited warranty ("limited warranty"). See id. ¶ 37, Ex. A (copy of the limited-warranty agreement). ¹ Under the limited warranty, GP promises to remedy any defects in the PrimeTrim by "[r]epair of the affected trim" or "[c]ash payment to the owner equivalent to the reasonable cost of repair or replacement of the affected trim with similar trim." Id., Ex. A. The limited warranty restricts repair costs and cash payments to no more than two times the original sales price of the affected trim. Id., Ex. A. Plaintiffs contend that the remedies under the limited warranty will not make them whole; therefore, the limited warranty fails of its essential purpose. See id. ¶ 46.

The limited warranty provides, in part:

With respect to any claim, damage or defect covered under the foregoing substrate limited warranty and subject to the maximum limits of compensation

subject to the maximum limits of compensation specified herein, Georgia-Pacific shall elect, at its sole discretion, to compensate the owners either by:

- Repair of the affected trim, or replacement of the affected trim with trim of the same or similar type and specification (including installation costs), without charge to the owner, OR
- Cash payment to the owner equivalent to the reasonable cost of repair or replacement of the affected trim with similar trim, provided however, that the "reasonable cost" of repair or replacement shall not exceed two times the original Georgia-Pacific sales price of the affected trim.

Sec. Am. Compl., Ex. A.

Nonetheless, on or about June 23, 2008, Kelly submitted a claim to GP under the express warranty. <u>Id.</u> ¶ 40. In August 2008, GP inspected Kelly's residence to investigate the warranty claim. <u>Id.</u> ¶ 41. GP and Kelly were unable to resolve the express-warranty claim.

In or around December 2008, the Wickers submitted a claim to GP under the express warranty. <u>Id.</u> ¶ 43. In or around March or April 2009, GP inspected the Wicker residence to investigate the warranty claim. <u>Id.</u> ¶ 44. GP and the Wickers were unable to resolve the express-warranty claim.

On October 15, 2008, Kelly sued defendants in New Hanover County Superior Court [D.E. 1-2]. Kelly claimed breach of express warranty, breach of implied warranty, negligence, violation of the Magnuson-Moss Act ("MMA"), 15 U.S.C. §§ 2301–2312, and violation of the North Carolina Unfair and Deceptive Trade Practices Act ("UDTPA"), N.C. Gen. Stat. §§ 75-1.1-75-16.2. See Compl. ¶¶ 51–96. Kelly sought certification as a class action, compensatory and statutory (treble) damages, equitable and injunctive relief, costs, attorney's fees, expert's fees, and pre-and post-judgment interest. Id. at 20 (prayer for relief); see id. ¶¶ 31–50.

On November 19, 2008, defendants removed the action to this court. Defendants are limited-liability companies organized and existing under the laws of the State of Delaware with their headquarters located in Atlanta, Georgia. The court has diversity jurisdiction under 28 U.S.C. § 1332(a). See Notice of Removal ¶¶ 7–10.

\*3 On December 18, 2008, defendants filed their answer [D.E. 8] and a partial motion to dismiss pursuant to Rule 12(b)(6) of the Federal Rules of Civil Procedure [D.E. 6]. On January 6, 2009, defendants filed a third-party complaint against Walter Thorpe McCartney and John Does 1–500 [D.E. 15]. According to the third-party complaint, McCartney built Kelly's home, and John Does 1–500 are the unknown

builders of the homes of the putative class members. Third-Party Compl. ¶¶ 5–6. According to defendants, the third-party defendants negligently installed the PrimeTrim. See id. ¶¶ 18, 21. Thus, if defendants are liable to plaintiffs and the putative class, defendants seek indemnification and contribution from the third-party defendants. Id. ¶¶ 2, 8, 21–49; see id. at 11 (prayer for relief).

On September 30, 2009, the court granted defendants' partial motion to dismiss. See Kelly, 671 F. Supp. 2d at 801. The court: (1) rejected Kelly's negligence claim due to North Carolina's economic-loss rule (id. at 790–96); (2) declined to address Kelly's implied-warranty claim (id. at 796–98); (3) rejected Kelly's argument that the limited warranty failed of its essential purpose or was unconscionable (id. at 798); (4) rejected Kelly's UDTPA claim (id. at 798–99); and (5) rejected Kelly's MMA claim (id. at 799–801).

On October 30, 2009, Kelly filed an amended complaint [D.E. 40]. On July 2, 2010, Kelly filed a second amended complaint [D.E. 69]. On December 6, 2009, and on July 12, 2010, GP answered the amended complaint [D.E. 49] and second amended complaint [D.E. 71], respectively. On January 6, 2009, GP filed a third-party complaint for indemnification and contribution against McCartney [D.E. 15]. On July 26, 2010, GP filed a third-party complaint for indemnification and contribution against Donaldson Construction [D.E. 73].

Defendants moved to dismiss the second amended complaint for failure to state a claim upon which relief can be granted as to most of plaintiffs' second amended complaint [D.E. 47]. Specifically, defendants contend that this court should dismiss all claims except plaintiffs' express-warranty claim [D.E. 47].

II.

A.

North Carolina substantive law controls plaintiffs' state-law claims. The standard for a motion to dismiss under Rule 12(b) (6), however, is a procedural matter controlled by federal law. See, e.g., Colgan Air, Inc. v. Raytheon Aircraft Co., 507 F.3d 270, 275 (4th Cir. 2007) (per curiam); Wilson v. Dryvit Sys., Inc., 206 F. Supp. 2d 749, 752 (E.D.N.C. 2002), aff'd, 71 Fed. Appx. 960 (4th Cir. 2003) (per curiam) (unpublished). A motion to dismiss under Rule 12(b)(6) tests the legal sufficiency of the complaint. See Fed. R. Civ. P. 12(b)(6); Ashcroft v. Iqbal, 129 S. Ct. 1937, 1949–52 (2009). A court

should grant a motion to dismiss under Rule 12(b)(6) if the complaint does not allege "enough facts to state a claim to relief that is plausible on its face." Bell Atl. Corp. v. Twombly, 550 U.S. 544, 570 (2007); Robinson v. Am. Honda Motor Co., 551 F.3d 218, 222 (4th Cir. 2009). "Specific facts are not necessary; the statement need only 'give the defendant fair notice of what the ... claim is and the grounds upon which it rests.' "Erickson v. Pardus, 551 U.S. 89, 93 (2007) (per curiam) (quoting Twombly, 550 U.S. at 555) (alteration in original). Accordingly, "[w]hile a plaintiff is not charged with pleading facts sufficient to prove [its] case, as an evidentiary matter, in [its] complaint, a plaintiff is required to allege facts that support a claim for relief." Bass v. E.I. DuPont de Nemours & Co., 324 F.3d 761, 765 (4th Cir. 2003); see Ashcroft, 129 S. Ct. at 1949-52.

Moreover, although the court "take[s] the facts in the light most favorable to the plaintiff," it "need not accept the legal conclusions drawn from the facts ... [or] unwarranted inferences, unreasonable conclusions, or arguments." Giarratano v. Johnson, 521 F.3d 298, 302 (4th Cir. 2008) (quotations omitted); see Ashcroft, 129 S. Ct. at 1949–52; Nemet Chevrolet, Ltd. v. Consumeraffairs.com, Inc., 591 F.3d 250, 255 (4th Cir. 2009). Furthermore, in analyzing a Rule 12(b)(6) motion to dismiss, a court may consider "documents incorporated into the complaint by reference, and matters of which a court may take judicial notice." Tellabs, Inc. v. Makor Issues & Rights, Ltd., 551 U.S. 308, 322 (2007).

B.

\*4 Initially, the court analyzes plaintiffs' negligence per se claim in count three. See Sec. Am. Compl. ¶¶ 83–100. In doing so, this court must predict how the North Carolina Supreme Court would analyze the claim. See Twin City Fire Ins. Co. v. Ben Arnold-Sunbelt Beverage Co. of S.C., 433 F.3d 365, 369 (4th Cir. 2005).

This court predicts that the North Carolina Supreme Court would apply the economic-loss rule to bar plaintiffs' negligence per se claim. See Kelly, 671 F. Supp. 2d at 790–96 (extensively analyzing history of economic-loss rule in North Carolina). Under North Carolina law, the economic-loss rule applies to negligence per se claims. See, e.g., Indem. Ins. Co. of N. Am. v. Am. Eurocopter LLC, No. 1:03-CV-949, 2005 WL 1610653, at \*16 (M.D.N.C. July 8, 2005) (unpublished); Nudelman v. J.A. Booe Bldg, Contractor,

Inc., No. COA02-267, 2003 WL 722190, at \*5 (N.C. App. Mar. 4, 2003) (unpublished); Warfield v. Hicks, 91 N.C. App. 1, 10, 370 S.E. 2d 689, 694 (1988). Moreover, the North Carolina Supreme Court would recognize the role of contract law (including the law of warranty) where an alleged defective product causes purely economic harm to the original purchaser of a home. See E. River S.S. Corp. v. Transamerica Delaval, Inc., 476 U.S. 858, 868 (1986); Redman v. John D. Brush & Co., 111 F.3d 1174, 1181-83 (4th Cir. 1997) (applying Virginia law); 2000 Watermark Ass'n., Inc. v. Celotex Corp., 784 F.2d 1183, 1185-87 (4th Cir. 1986) (applying South Carolina law); Ellis-Don Constr., Inc. v. HKS, Inc., 353 F. Supp. 2d 603, 606-07 (M.D.N.C. 2004) ("North Carolina's economic loss rule bars claims in tort for purely economic losses in the sale of goods covered by contract law, including the UCC.... [T]he rule operates to preclude recovery in tort for purely economic damages when a contract or the UCC operates to allocate the risk of such damages."); Wilson, 206 F. Supp. 2d at 753-54 (collecting cases); Moore v. Coachmen Indus., Inc., 129 N.C. App. 389, 401-02, 499 S.E.2d 772, 780 (1998). Furthermore, the court rejects plaintiffs' argument that their claim fits within one of the four exceptions to the economic-loss rule that the North Carolina Supreme Court described in N.C. State Ports Auth. v. Lloyd A. Frye Roofing Co., 294 N.C. 73, 82, 240 S.E.2d 345, 350–51 (1978), rejected in part on other grounds by Trs. of Rowan Technical Coll. v. J. Hyatt Hammond Assocs., Inc., 313 N.C. 230, 328 S.E.2d 274 (1985). Simply put, as a federal court sitting in diversity, the court declines to expand North Carolina law in the way that plaintiffs propose. See, e.g., Time Warner Entm't-Advance/Newhouse P'ship v. Carteret-Craven Elec. Membership Corp., 506 F.3d 304, 314-15 (4th Cir. 2007) (sitting in diversity, a federal court should not create or expand a state's common law or public policy). Accordingly, North Carolina's economic-loss rule bars plaintiffs' negligence per se claim in count three.

Alternatively, the negligence per se claim fails because the Building Code provisions on which plaintiffs rely do not impose a duty on defendants. See, e.g., Olympic Prods. Co. v. Roof Sys. Inc., 88 N.C. App. 315, 329, 363 S.E.2d 367, 375 (1988); see also Talley v. Danek Med., Inc., 179 F.3d 154, 158-59 (4th Cir. 1999). Hence, the court grants defendants' motion to dismiss plaintiffs' negligence per se claim in count three.

C.

\*5 Next, the court addresses plaintiffs' implied-warranty claim in count two. See Sec. Am. Compl. ¶¶ 70–82. Under North Carolina common law, privity of contract is generally required to assert an express-or implied-warranty claim. See, e.g., Kinlaw v. Long Mfg. N.C., Inc., 298 N.C. 494, 496-97, 259 S.E.2d 552, 554 (1979); Terry v. Double Cola Bottling Co., 263 N.C. 1, 3, 138 S.E.2d 753, 754 (1964); Atl. Coast Mech., Inc. v. Arcadis, Geraghty & Miller of N.C., Inc., 175 N.C. App. 339, 345-46, 623 S.E.2d 334, 339-40 (2006). "Except where the barrier of privity has been legislatively or judicially removed, the absence of a contractual relationship between the seller or manufacturer of an allegedly defective product and the person injured by it continues to preclude products liability actions for breach of express and implied warranties." Crews v. W.A. Brown & Son, Inc., 106 N.C. App. 324, 331, 416 S.E.2d 924, 929 (1992).

For example, in Kinlaw the North Carolina Supreme Court held that a remote purchaser may bring an express-warranty claim for economic loss against a manufacturer if the manufacture's express warranty is directed to the end user. See Kinlaw, 298 N.C. at 498–502, 259 S.E.2d at 555–58; see also Bernick v. Jurden, 306 N.C. 435, 448, 293 S.E.2d 405, 413 (1982). The North Carolina Supreme Court, however, has not extended Kinlaw to implied warranties. See, e.g., Energy Investors Fund, LP v. Metric Constructors, Inc., 351 N.C. 331, 338, 525 S.E.2d 441, 446 (2000); cf. Gregory v. Atrium Door & Window Co., 106 N.C. App. 142, 144, 415 S.E.2d 574, 575 (1998) (inviting the General Assembly or the North Carolina Supreme Court to examine "whether the privity requirement for implied warranties is still good policy").

Similarly, in 1979, the North Carolina General Assembly enacted the Products Liability Act ("Act"). See 1979 N.C. Sess. Laws 687. The Act defines a "product liability action" as "any action brought for or on account of personal injury, death or property damage caused by or resulting from the manufacture, construction, design, formulation, development of standards, preparation, processing, assembly, testing, listing, certifying, warning, instructing, marketing, selling, advertising, packaging, or labeling of any product." See N.C. Gen. Stat. § 99B-1. The Act partially abrogates the privity requirement for implied-warranty claims against manufacturers when the action is "brought for or on account of personal injury, death or property damage caused by or resulting from the manufacture ... of any product." Id. § 99B-1(3); see id. § 99B-2(b); DeWitt v. Eveready Battery Co., 355 N.C. 672, 682, 565 S.E.2d 140, 146 (2002); Tetterton v. Long Mfg. Co., 314 N.C. 44, 50, 332 S.E.2d 67, 71 (1985).<sup>2</sup>

However, when a plaintiff asserts an implied-warranty claim seeking only economic loss, North Carolina still requires privity of contract. See, e.g., Energy Investors Fund, L.P., 351 N.C. at 338, 525 S.E.2d at 446; Atl. Coast Mech., Inc., 175 N.C. App. at 345-46, 623 S.E.2d at 339-40; Reece v. Homette Corp., 110 N.C. App. 462, 465, 429 S.E.2d 768, 769 (1993) (requiring privity "where the alleged defects of the product manufactured by defendant caused neither personal injury nor damage to property other than to the manufactured product itself"); Gregory, 106N.C. App. at 144.415 S.E.2d at 575; Sharrard, McGee & Co., P.A. v. Suz's Software, Inc., 100 N.C. App. 428, 432, 396 S.E.2d 815, 817–18 (1990) ("[O]utside the exceptions created by [N.C. Gen. Stat. § 99B], the general rule is that privity is required to assert a claim for breach of an implied warranty involving only economic loss."); Cato Equip. Co. v. Matthews, 91 N.C. App. 546, 549, 372 S.E.2d 872, 874 (1988); see also AT&T Corp. v. Med. Review of N.C., Inc., 876 F. Supp. 91, 95 (E.D.N.C. 1995).

2 North Carolina does not recognize strict liability in products-liability actions. See, e.g., N.C. Gen. Stat § 99B-1.1; Smith v. Fiber Controls Corp., 300 N.C. 669, 678, 268 S.E.2d 504, 509-10 (1980); Bryant v. Adams, 116 N.C. App. 448, 472-73, 448 S.E.2d 832, 845 (1994).

\*6 In count two, plaintiffs seek to recover for breach of implied warranty. See Sec. Am. Compl. ¶¶ 70-82. Specifically, plaintiffs seek damages for economic loss that they suffered due to their builder's use of PrimeTrim in building their houses. See Sec. Am. Compl. ¶ 35; see also id. ¶¶ 55-69. Under North Carolina law, to recover under this implied-warranty theory, plaintiffs and defendants must be in privity of contract. See, e.g., Energy Investors Fund, L.P., 351 N.C. at 338, 525 S.E.2d at 446; Kinlaw, 298 N.C. at 496-97, 259 S.E.2d at 554; Atl. Coast Mech., Inc., 175 N.C. App. at 345-46, 623 S.E.2d at 339-40. In order to meet this requirement, plaintiffs allege that they are "either in privity with GP or are third-party beneficiaries of the contracts entered into between Plaintiffs' and Class Members' builders, contractors, subcontractors, and/or agents, and GP." Sec. Am. Compl.¶ 76.

"Privity is a child of contract law, delivered by the courts to limit the responsibilities of contracting parties to those persons consensually involved in the primary transaction." Kinlaw, 298 N.C. at 497, 259 S.E.2d at 554. "It was originally felt that without such a limitation on liability, the most absurd and outrageous consequences would ensue in litigation caused by a flood of spurious claims." Id., 259 S.E.2d at 554 (quotation omitted). Privity of contract "exists between the original covenanting parties." Runyon v. Paley, 331 N.C. 293, 302, 416 S.E.2d 177, 184 (1992).

Plaintiffs are not parties to the original contracts with GP. See Sec. Am. Compl. ¶¶ 20, 40–45, 62. Rather, GP contracted with the builders of plaintiffs' homes. Thus, plaintiffs are not in actual privity with GP. Plaintiffs, however, seek to establish implied privity of contract by alleging that they are thirdparty beneficiaries to the contracts between GP and plaintiffs' builders and thereby state an implied-warranty claim. See Sec. Am. Compl. ¶¶ 19–20, 70–82. In support, plaintiffs cite Coastal Leasing Corp. v. O'Neal, where the North Carolina Court of Appeals allowed a third-party beneficiary to proceed with an implied-warranty claim under the North Carolina Uniform Commercial Code against a manufacturer. 103 N.C. App. 230, 236, 405 S.E.2d 208, 212 (1991). Plaintiffs also note that the North Carolina Court of Appeals relied upon Coastal Leasing Corp. to imply privity in other cases involving an alleged third-party beneficiary. See, e.g., LSB Fin. Servs. v. Harrison, 144 N.C. App. 542, 548, 548 S.E.2d 574, 579 (2001) (determining that an ex-employee was a third-party beneficiary to an arbitration clause in a NASD broker's registration form); Murray v. Nationwide Mut. Ins. Co., 123 N.C. App. 1, 15, 472 S.E.2d 358, 366 (1996) (determining that an injured driver was a third-party beneficiary to an insurance contract between the tortfeasor and the tortfeasor's insurance company).

In reply, defendants contend that the cited cases are distinguishable and that, under Kinlaw and its progeny, the North Carolina Supreme Court would require actual contractual privity to support plaintiffs' implied-warranty claim. See Defs.' Reply 4-5. According to defendants, plaintiffs' "implied warranty claim falls into ... [a] gap ... between Kinlaw and Section 99B—where actual contractual privity is still required." Id. at 5.

The court agrees that the North Carolina Supreme Court's decision in Energy Investors Fund, L.P., 351 N.C. at 338, 525 S.E.2d at 446, and Kinlaw, 298 N.C. at 498-502, 259 S.E.2d at 555–58, require actual privity to state an impliedwarranty claim for recovery of economic loss. See also Atl. Coast Mech., Inc., 175 N.C. App. at 345-46, 623 S.E.2d at 339-40; Reece, 110 N.C. App. at 465, 429 S.E.2d at 769; Gregory, 106 N.C. App. at 144, 415 S.E.2d at 575. Moreover, Coastal Leasing does not alter this conclusion.

\*7 In Coastal Leasing, a restaurant owner leased an industrial ice machine and "directly negotiated" the purchase

with the seller (who also was the manufacturer). 103 N.C. App. at 235, 405 S.E.2d at 212. During the negotiations, the restaurant owner obtained certain express warranties from the seller/manufacturer. The seller/manufacturer then sold the ice machine to a leasing company, which in turn leased the machine to the restaurant owner. The ice machine failed to operate as promised, and the restaurant owner had to purchase ice from another source. On these unique facts, where the restaurant owner directly participated in the sales transaction with the seller/manufacturer and was seeking more than economic loss, the North Carolina Court of Appeals held that the restaurant was an intended, direct third-party beneficiary of the contract between the seller/ manufacturer and the leasing company. Id. at 235-36, 405 S.E.2d at 211-12. Thus, the restaurant owner could seek damages from the manufacturer/seller.

Coastal Leasing does not help plaintiffs. Unlike the restaurant owner in Coastal Leasing, plaintiffs admit that they did not negotiate with GP concerning the purchase of PrimeTrim. Moreover, plaintiffs seek to recover only economic loss. Thus, Kinlaw and its progeny control as to the viability of plaintiffs' breach-of-implied-warranty claim. Furthermore, as a federal court sitting in diversity, the court declines to extend Coastal Leasing to the facts in this case. See, e.g., Time Warner Entm't—Advance/Newhouse P'ship, 506 F.3d at 314–15. Accordingly, the court dismisses plaintiffs' implied-warranty claim in count two.<sup>3</sup>

In light of this conclusion, the court does not address whether the contract was entered into for their direct, and not incidental, benefit. See, e.g., Vogel v. Reed Supply Co., 277 N.C. 119, 129, 177 S.E.2d 273, 279 (1970); Hospira Inc. v. Alphagary Corp., 194 N.C. App. 695, 702–03, 671 S.E.2d 7, 13 (2009), review denied, 682 S.E.2d 210 (N.C. 2009); Michael v. Huffman Oil Co., Inc., 190 N.C. App. 256, 269–70, 661 S.E.2d 1, 10–11 (2008); Revels v. Miss Am. Org., 182 N.C. App. 334, 336, 641 S.E.2d 721, 723 (2007).

D.

Next, the court addresses plaintiffs' latest contention that the express warranty fails of its essential purpose or is unconscionable. The court has already concluded that the express warranty does not fail of its essential purpose and the court rejects plaintiffs' latest arguments to the contrary. See Kelly, 671 F. Supp. 2d at 798.

As for whether the express warranty is unconscionable (Sec. Am. Compl. ¶¶ 12(h), 61–62), the court also addressed and rejected that argument. See Kelly, 671 F. Supp. 2d at 798. To the extent that plaintiffs were unsure of this court's conclusion concerning unconscionability, the issue of unconscionability is a question of law for the court. See, e.g., Rite Color Chem. Co. v. Velvet Textile Co., 105 N.C. App. 14, 21, 411 S.E.2d 645, 649 (1992). Given that the damage limitation in the express warranty provides a fair remedy, that the sales transaction for the PrimeTrim arose in a commercial setting, that the builders had choices other than Prime Trim, and that plaintiffs seek to recover only property damage from defendants, the express warranty is not unconscionable. See, e.g., Moore, 129 N.C. App. at 398-99, 499 S.E.2d at 778; Byrd Motor Lines, Inc. v. Dunlop Tire & Rubber Corp., 63 N.C. App. 292, 296–97, 304 S.E.2d 773, 776–77 (1983).

E.

Next, defendants seek to dismiss plaintiffs' UDTPA claim in count four. See Sec. Am. Compl. ¶¶ 101–15. Defendants make two arguments: (1) plaintiffs fail to state a claim for relief under the UDTPA; and (2) the economic-loss rule bars the UDTPA claim. Initially, the court addresses whether plaintiffs fail to state a UDTPA claim.

To state a claim under the UDTPA, plaintiff must show (1) an unfair or deceptive act or practice (2) in or affecting commerce (3) which proximately caused actual injury to the plaintiff or to his business. See, e.g., N.C. Gen. Stat. § 75-1.1; Walker v. Fleetwood Homes of N.C., Inc., 362 N.C. 63, 71-72, 653 S.E.2d 393, 399 (2007); <u>Dalton v. Camp</u>, 353 N.C. 647, 656-57, 548 S.E.2d 704, 710-11 (2001); RD&J Props, v. Lauralea-Dilton Enters., LLC, 165 N.C. App. 737, 748, 600 S.E.2d 492, 500 (2004). The conduct must be immoral, unethical, oppressive, unscrupulous, or substantially injurious to consumers. See, e.g., Gilbane Bldg. Co. v. Fed. Reserve Bank, 80 F.3d 895, 902 (4th Cir. 1996); Branch Banking & Trust Co. v. Thompson, 107 N.C. App. 53, 61, 418 S.E.2d 694, 700 (1992). Whether an act or practice is unfair or deceptive under the UDTPA is a question of law for the court. See, e.g., Tucker v. Boulevard at Piper Glen LLC, 150 N.C. App. 150, 153, 564 S.E.2d 248, 250 (2002); Norman Owen Trucking, Inc. v. Morkoski, 131 N.C. App. 168, 177, 506 S.E.2d 267, 273 (1998).

\*8 Under North Carolina law, a breach of warranty alone is insufficient to state a UDTPA claim. See, e.g., Washburn v.

Yadkin Valley Bank & Trust Co., 190 N.C. App. 315, 325, 660 S.E.2d 577, 584-85 (2008); Se. Shelter Corp. v. BTU, Inc., 154 N.C. App. 321, 330, 572 S.E.2d 200, 206 (2002); Mitchell v. Linville, 148 N.C. App. 71, 74, 557 S.E.2d 620, 623 (2001); Norman Owen Trucking, 131 N.C. App. at 177, 506 S.E.2d at 273; Branch Banking & Trust Co., 107 N.C. App. at 62, 418 S.E.2d at 700. Rather, a party must allege some type of egregious or aggravating circumstances. See Norman Owen Trucking, 131 N.C. App. at 177, 506 S.E.2d at 273; see also Broussard v. Meineke Disc. Muffler Shops, Inc., 155 F.3d 331, 347 (4th Cir. 1998) ("The courts differentiate between contract and deceptive trade practice claims, and relegate claims regarding the existence of an agreement, the terms contained in an agreement, and the interpretation of an agreement to the arena of contract law." (quotation omitted)); Bartolomeo v. S.B. Thomas, Inc., 889 F.2d 530, 534-36 (4th Cir. 1989); PCS Phosphate Co. v. Norfolk S. Corp., 520 F. Supp. 2d 705, 717–18 (E.D.N.C. 2007), aff'd, 559 F.3d 212 (4th Cir. 2009). "North Carolina courts have repeatedly held that a mere breach of contract, even if intentional," does not rise to an unfair or deceptive trade practice. Broussard, 155 F.3d at 347 (quotation omitted); see PCS Phosphate Co., 559 F.3d at 224. Moreover, "[w]here an unfair or deceptive practice claim is based upon an alleged misrepresentation by the defendant, the plaintiff must show 'actual reliance' on the alleged misrepresentation in order to establish that the alleged misrepresentation 'proximately caused' the injury of which plaintiff complains." Sunset Beach Dev., LLC v. AMEC, Inc., 196 N.C. App. 202, 211, 675 S.E.2d 46, 53 (2009) (quotation omitted); see Tucker, 150 N.C. App. at 154, 564 S.E.2d at 251.

Here, defendants' failure to address plaintiffs' warranty claims to their satisfaction or the design of a purportedly defective product do not rise to "substantial aggravating circumstances" to support plaintiffs' UDTPA claim. See, e.g., PCS Phosphate Co., 559 F.3d at 224; Broussard, 155 F.3d at 346–47; Branch Banking & Trust Co., 107 N.C. App. at 62, 418 S.E.2d at 700. Furthermore, to the extent that plaintiffs cite defendants' allegedly deceptive marketing materials (Sec. Am. Compl.¶¶ 103–05), the UDTPA claim fails because plaintiffs do not allege facts that show that they actually relied on any alleged misrepresentation or that the misrepresentation proximately caused their alleged damage. See, e.g., Kelly, 671 F. Supp. 2d at 798–99; Dalton, 353 N.C. at 656–57, 548 S.E.2d at 711; Sunset Beach Dev., LLC, 196 N.C. App. at 211, 675 S.E.2d at 53. Thus, the court grants defendants' motion to dismiss the UDTPA claim.

In light of this conclusion, the court does not address whether the economic-loss rule bars plaintiffs UDTPA claim. Cf. Bussian v. DaimlerChrysler Corp., 411 F. Supp. 2d 614, 625 (M.D.N.C. 2006).

III.

As explained above, the court GRANTS defendants' partial motion to dismiss the second amended complaint [D.E. 47].

SO ORDERED. This 31st day of August 2010.

# **All Citations**

Not Reported in Fed. Supp., 2010 WL 11579013

**End of Document** 

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# **Tab 17**

2020 WL 3542305 Only the Westlaw citation is currently available. United States District Court, D. New Jersey, Camden Vicinage.

> K.J., individually and on behalf of K.J., Jr., et al., Plaintiffs,

GREATER EGG HARBOR REGIONAL HIGH SCHOOL DISTRICT BOARD OF EDUCATION, et al., Defendants.

> Civil No. 14-145 (RBK/JS) | Signed 06/30/2020

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### **OPINION**

**KUGLER**, United States District Judge

\*1 This matter comes before the Court upon Defendants' Motion for Reconsideration (Doc. 180). Defendants seek reconsideration of the Court's December 16, 2019 Order (Doc. 178) that denied in part Defendants' motion for summary judgment. For the reasons contained herein, Defendants' Motion for Reconsideration is DENIED.

### I. BACKGROUND

An extensive factual history of this case has been set out in previous opinions (Docs. 51, 177) and is not repeated here. In brief, a high school student named K.J. and his family (collectively "Plaintiffs") brought this action against K.J.'s school district and affiliated administrators, teachers, and staff (collectively "Defendants"). Plaintiffs allege that Defendants violated a number of K.J.'s rights in connection with two

incidents that resulted in school suspensions in 2011 and 2012. (Doc. 180-2 at 4.)

Since Plaintiffs filed this suit in January 2014, this case has weathered numerous amended complaints, motions to dismiss, and motions for summary judgment. The Court's Opinion and Order dated December 16, 2019 (Docs. 177, 178), which granted in part and denied in part Defendants' latest request for summary judgment, is the subject of Defendants' present motion for reconsideration.

The December 2019 Order granted Defendants' motion for summary judgment in part, as to the following counts: Count III (Violation of NJCRA) only as to the First Amendment and Fourth Amendment violations alleged, Count V (§ 1983 claim for violation of the Fourth Amendment), Count VI (§ 1983 claim for violation of the First Amendment), Count VII (§ 1983 claim for violation of the Fourteenth Amendment) only as to the alleged due process violations following the December 2012 incident, Count XII (NJLAD hostile learning environment), and Count XVI (IIED). (Doc. 178.) It denied Defendants' motion for summary judgment as to all other counts. (*Id.*)

Defendants now ask the Court to reconsider its denial of summary judgment as to Counts I and II, portions of Count III and Count VII, Count XI, Count XIII, Count XIV, and Count XX.

# II. LEGAL STANDARD

Motions for reconsideration are governed by Local Civil Rule 7.1(i), which allows a party to seek reconsideration by the Court in matters in which the party believes the judge has "overlooked." See Carney v. Pennsauken Twp. Police Dep't, Civ. No. 11-7366, 2013 WL 4501454, at \*1 (D.N.J. Aug. 21, 2013) (citations omitted). "The standard for reargument is high and reconsideration is to be granted only sparingly." Yarrell v. Bartkowski, Civ. No. 10-5337, 2012 WL 1600316, at \*3 (D.N.J. May 7, 2012). To be successful on a motion for reconsideration, a petitioner has the burden to demonstrate: "(1) an intervening change in the controlling law; (2) the availability of new evidence that was not available when the court [issued its order]; or (3) the need to correct a clear error of law or fact or to prevent manifest injustice." Max's Seafood Cafe ex. rel. Lou-Ann v. Quinteros, 176 F.3d 669, 677 (3d Cir. 1999). "The word 'overlooked' is the operative term in the Rule." Bowers v. NCAA, 130 F. Supp. 2d 610, 612 (D.N.J. 2001). The Court will grant a motion for reconsideration only where it overlooked a factual or legal issue that may alter the

disposition of the matter. *See United States v. Compaction Sys. Corp.*, 88 F. Supp. 2d 339, 345 (D.N.J. 1999); L. Civ. R. 7.1(i).

### III. DISCUSSION

\*2 In moving for reconsideration, Defendants argue that the Court erroneously denied summary judgment on the Counts referenced above. In opposition, Plaintiffs argue that Defendants' motion for reconsideration is untimely under the applicable rule—Local Civil Rule 7.1(i)—and should be denied. (Doc. 181 at 6–7.) The Court agrees with Plaintiffs.

Under Local Civil Rule 7.1(i), motions for reconsideration must be "filed within 14 days after the entry of the order or judgment on the original motion by the Judge." L. Civ. R. 7.1(i) Here, the Order in question was entered on December 16, 2019. (Doc. 178.) Defendants filed the Motion for Reconsideration (Doc. 180) on January 6, 2020—twenty-one days after entry of the order, and thus past the deadline set out in Rule 7.1(i).

In their reply brief, Defendants argue that the motion is not untimely because it is governed by the longer, 28-day timeline set out in Federal Rule of Civil Procedure 59(e). (Doc. 182 at 4–5.) Further, although they did not mention Federal Rule of Civil Procedure 60 in their motion, Defendants also include a single sentence in their reply brief stating that the motion was brought pursuant to Rule 60. (Doc. 182 at 4.) However, Defendants do not elaborate on the requirements of Rule 60, nor do they provide any explanation of how their motion satisfies Rule 60.<sup>1</sup>

The entirety of Defendants' reference to Rule 60 is: "Defendants file the instant Motion for Reconsideration pursuant to Federal Court Rule 59(e) and 60." (Doc. 182 at 4.)

The Court first addresses Defendants' passing reference to Rule 60. "It is well-established that a party cannot raise an argument for the first time in a reply brief." *Maliandi v. Montclair State Univ.*, Civ. No. 14-1398, 2017 WL 935160, at \*5 (D.N.J. Mar. 9, 2017), *aff'd*, 2017 WL 3023205 (D.N.J. July 17, 2017) (declining to consider a party's argument that Rule 60 applied when the argument was raised for the first time in a reply brief). *See also Laborers' Int'l Union of N. Am., AFL-CIO v. Foster Wheeler Energy Corp.*, 26 F.3d 375, 398 (3d Cir. 1994) (finding that "[a]n issue is waived unless a party raises it in its opening brief," and finding "a passing reference to an issue" to be insufficient).

Defendants' brief filed in support of their motion clearly alleges that the motion for reconsideration is governed by Local Rule 7.1(i) and Rule 59(e)—the brief does not include any mention of Rule 60. (Doc. 180-2 at 2.) In their reply brief, Defendants then make a "passing reference" to Rule 60. However, they do not include any arguments alleging that they meet Rule 60's grounds for relief. Accordingly, because Defendants raise Rule 60 in their reply and then fail to make any argument as to its application, the Court does not consider the possible application of Rule 60 to this motion.

Turning next to Defendants' argument that the 28-day timeline in Rule 59(e) controls, rather than the 14-day timeline in Local Rule 7.1(i), the Court finds that this argument also fails. Rule 59(e), titled "Motion to Alter or Amend a Judgment," dictates that "[a] motion to alter or amend a judgment must be filed no later than 28 days after the entry of the judgment." Fed. R. Civ. P. 59(e). Courts construe the term "judgment" in Rule 59(e) to mean a *final* judgment, not an interlocutory order. *Schlafly v. Eagle Forum*, Civ. No. 17-2522, 2020 WL 2790519, at \*3 (D.N.J. May 30, 2020) (collecting cases).

\*3 Where a party moves for reconsideration of an order denying summary judgment, this Court has repeatedly held that "[t]he provisions of Rule 59 are designed to address orders rendering a final judgment, not interlocutory orders denying summary judgment," and where "no final judgment has been entered ... the provisions of Rule 59, and its 28-day time limit, are inapplicable." Mitchell v. Twp. of Willingboro Municipality Gov't, 913 F.Supp.2d 62, 78 (D.N.J. 2012). See also Zitter v. Petruccelli, Civ. No. 15-6488, 2017 WL 1837850, at \*2 (D.N.J. May 8, 2017) (holding that "Local Civil Rule 7.1(i), and not Fed. R. Civ. P. 59(e)," governs motions for reconsideration of an interlocutory order); Jones v. Sanko Steamship Co., Ltd, Civ. No. 10-6787, 2016 WL 819618 (D.N.J. Mar. 2, 2016) (holding that, where "no final judgment has been entered ... the provisions of Rule 59(e), and its 28-day time limit, have no application ... Rather, Local Civil Rule 7.1(i) provides the proper procedural mechanism for reconsideration of this Court's interlocutory summary judgment decision").

Because Defendants seek reconsideration of an "interlocutory order[ ] denying summary judgment," rather than reconsideration of a final judgment, the 14-day time limit in Rule 7.1(i) controls. *Mitchell*, 913 F.Supp.2d at 78. Under this standard, Defendants' motion is untimely, and will be denied accordingly. *See Schlafly*, 2020 WL 2790519, at \*6 (noting

that "courts within this district routinely deny untimely ... Local Civil Rule 7.1(i) motions," and noting further that "the Third Circuit has upheld the denial of untimely ... Local Civil Rule 7.1(i) motions") (collecting cases).

For the reasons detailed above, Defendants' Motion for Reconsideration (Doc. 180) is DENIED. An accompanying Order shall issue.

# **All Citations**

Slip Copy, 2020 WL 3542305

**End of Document** 

IV. CONCLUSION

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# **Tab 18**

KeyCite Yellow Flag - Negative Treatment
Declined to Follow by City of Greenville, Ill. v. Syngenta Crop Protection,
Inc., S.D.Ill., November 18, 2010

374 Fed.Appx. 257
This case was not selected for publication in West's Federal Reporter.
See Fed. Rule of Appellate Procedure 32.1 generally governing citation of judicial decisions issued on or after Jan. 1, 2007. See also U.S.Ct. of Appeals 3rd Cir. App. I, IOP 5.1, 5.3, and 5.7.
United States Court of Appeals,
Third Circuit.

Ruth KORONTHALY, individually and on behalf of all others similarly situated, Appellant

V.

L'OREAL USA, INC., a New York Corporation; The Procter and Gamble Distributing LLC, an Ohio Corporation.

> No. 08–4625. | Argued Nov. 10, 2009. | Opinion Filed: March 26, 2010.

### **Synopsis**

**Background:** Purchaser of lipstick products containing lead brought class action against companies that manufactured, marketed, and distributed the products. Defendants filed motions to dismiss. The United States District Court for the District of New Jersey, Dennis M. Cavanaugh, J., 2008 WL 2938045, granted the motions and subsequently denied plaintiff's motions for reconsideration and to file a second amended complaint. Plaintiff appealed.

**Holdings:** The Court of Appeals, Roth, Circuit Judge, held that:

[1] plaintiff's subjective allegation that the trace amounts of lead in the lipsticks were unacceptable to her was not an injury-in-fact sufficient to confer constitutional standing, and

[2] to the extent plaintiff contended that she lost the "benefit of the bargain" in purchasing the lipsticks, she did not demonstrate a concrete injury-in-fact.

Affirmed.

West Headnotes (2)

# [1] **Products Liability** • Nature of Injury or Damage

**Products Liability** ← Persons Entitled to Sue **Products Liability** ← Cosmetics, soaps, and hair-care products

Subjective allegation made by purchaser of lipstick products containing lead, that the trace amounts of lead in the lipsticks were unacceptable to her, was not an injury-infact sufficient to confer constitutional standing; purchaser's argument that she was misled into purchasing unsafe lipstick products was belied by Food and Drug Administration (FDA) report finding that lead levels in manufacturers' lipsticks were not dangerous and therefore did not require warnings, and purchaser conceded that she had suffered no adverse health effects from using the lipsticks. Fed.Rules Civ.Proc.Rule 12(b)(1), 28 U.S.C.A.

18 Cases that cite this headnote

# [2] Sales 🕪 Standing

To the extent purchaser of lipstick products containing lead contended that she lost the "benefit of the bargain" in purchasing the lipsticks, she did not demonstrate a concrete injury-in-fact, as required for standing; because her purchases were not made pursuant to a contract, she could not have been denied the benefit of any bargain, and purchaser did not allege that she received a product that failed to work for its intended purpose or was worth objectively less than what one could reasonably have expected. Fed.Rules Civ.Proc.Rule 12(b) (1), 28 U.S.C.A.

### 35 Cases that cite this headnote

\*258 On Appeal from the United States District Court for the District of New Jersey (District Court No. 2–07–cv–05588), District Judge: Dennis M. Cavanaugh.

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Michael R. McDonald, Esquire (Argued), Damian V. Santomauro, Esquire, Gibbons, P.C., Newark, NJ, for Appellee The Procter & Gamble Distributing, LLC.

Before: AMBRO, GARTH, and ROTH, Circuit Judges.

# **OPINION**

# **ROTH**, Circuit Judge:

\*\*1 Ruth Koronthaly appeals from the District Court's order granting defendant Procter & Gamble Company's ("P & G") motion to dismiss pursuant to Federal Rule of Civil Procedure 12(b)(1) for lack of standing and defendant L'Oreal USA, Inc.'s ("L'Oreal") motion to dismiss pursuant to Rule 12(b) (6). We exercise plenary review over a grant of a motion to dismiss for lack of standing and review the factual elements underlying the standing determination for clear error. *Goode v. City of Phila.*, 539 F.3d 311, 316 (3d Cir.2008). The burden of proving each standing element rests with the plaintiff. *Danvers Motor Co., Inc. v. Ford Motor Co.*, 432 F.3d 286, 291 (3d Cir.2005). We assume the parties' familiarity with the factual and procedural history, which we describe only as necessary to explain our decision. We will affirm the District Court's order.

Koronthaly purchased lipstick products manufactured, marketed, and distributed by appellees L'Oreal. and P &

G. These lipstick products contain lead. The FDA does not regulate the presence of lead in lipstick, but Koronthaly asserts that the lipstick contains lead in far greater amounts than permitted in candy by the FDA. Neither the packaging nor the products themselves contained any indication that the lipstick contained any lead.

Koronthaly did not know when she purchased the products that they contained any lead, and when she learned of the lead content she immediately stopped using them. Moreover, had she known of the lead she would not have purchased the products.

In November 2007, Koronthaly filed a class action complaint in the District Court for the District of New Jersey. She invoked the District Court's jurisdiction under the Class Action Fairness Act, 28 U.S.C. § 1332(d)(2). After it was amended in March 2008, her complaint asserted claims for: (1) violation of the New Jersey Consumer Fraud Act, N.J.S.A. § 56:8–1 et seq.; (2) breach of implied warranty under the New Jersey UCC; (3) breach of implied warranty under the Magnuson–Moss Warranty Act, 15 U.S.C. § 2310(d)(1); (4) strict liability; (5) negligence per se; (6) unjust enrichment; and (7) injunctive relief.

\*259 L'Oreal and P & G filed motions to dismiss pursuant to Fed.R.Civ.P. 12(b)(6) and 12(b)(1), respectively. On July 25, 2008, the District Court granted those motions, finding that Koronthaly lacked standing to pursue the action. On October 24, 2008, the District Court denied Koronthaly's motion for reconsideration, and her motion for leave to file a second amended complaint. Koronthaly then filed a timely notice of appeal.

To prove constitutional standing, Koronthaly must demonstrate (1) an injury-in-fact that is actual or imminent and concrete and particularized, not conjectural or hypothetical, (2) that is fairly traceable to the defendant's challenged conduct, and (3) is likely to be redressed by a favorable judicial decision. *Summers v. Earth Island Inst.*, — U.S. ——, 129 S.Ct. 1142, 1149, 173 L.Ed.2d 1 (2009). In this case, standing founders on the first requirement, injury-in-fact.

\*\*2 [1] Koronthaly's argument that she was misled into purchasing unsafe lipstick products is belied by the FDA's report finding that the lead levels in the Defendants' lipsticks were not dangerous and therefore did not require warnings. Moreover, Koronthaly concedes that she has suffered no

adverse health effects from using the lipsticks. Koronthaly therefore has asserted only a subjective allegation that the trace amounts of lead in the lipsticks are unacceptable to her, not an injury-in-fact sufficient to confer Article III standing. See Lujan v. Defenders of Wildlife, 504 U.S. 555, 564, 112 S.Ct. 2130, 119 L.Ed.2d 351 (1992) (injury-in-fact must be accompanied by "continuing, present adverse effects") (citation omitted); Georgine v. Amchem Prods., Inc., 83 F.3d 610, 636 (3d Cir.1996) (Wellford, J., concurring) ("Fear and apprehension about a possible future physical or medical consequence ... is not enough to establish an injury in fact.").

[2] Furthermore, to the extent that Koronthaly contends that the injury-in-fact was the loss of her "benefit of the bargain," she mistakenly relies on contract law. *See Rivera v. Wyeth–Ayerst Labs.*, 283 F.3d 315, 319–21 (5th Cir.2002) (plaintiff, whose only claim was that she "would like her

money back" for having purchased a product that failed to make certain disclosures and allegedly was defective, did not have an injury-in-fact sufficient to create standing). Her lipstick purchases were not made pursuant to a contract, and therefore she could not have been denied the benefit of any bargain. Absent any allegation that she received a product that failed to work for its intended purpose or was worth objectively less than what one could reasonably expect, Koronthaly has not demonstrated a concrete injury-in-fact.

For the foregoing reasons, we will affirm the order of the District Court granting the Defendants' motions to dismiss.

# **All Citations**

374 Fed.Appx. 257, 2010 WL 1169958

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Government Works.

# **Tab 19**

# 2010 WL 11640212

Only the Westlaw citation is currently available.
United States District Court, E.D. Kentucky,
Northern Division.
at Covington.

Belinda LINDSEY and Sheldon Lindsey and William R. Rahschulte, Together on Behalf of Themselves and a Class of Similarly Situated Persons, Plaintiffs

v.

AMERICAN SECURITY INSURANCE COMPANY and American Bankers Insurance Co. of Florida, Individually and as Representatives of a Class of American Security Insurance Company Insurers, Defendants

> CIVIL ACTION NO. 08-126-DLB | Signed 03/29/2010

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# **MEMORANDUM ORDER**

# David L. Bunning, United States District Judge

\*1 This case represents another of the proposed class actions challenging the imposition of local government premium taxes. This case is one of the later-filed actions, having been brought one day prior to the effective date of new Kentucky statutory provisions directed at this local

government premium taxation issue. There are three threshold motions pending before the Court for review. Defendants have not yet answered in this case.

# Motion to Dismiss for Failure to State a Claim

The first motion is Defendants' general Motion to Dismiss under Civil Rule 12(b)(6). (Doc. #19). The motion raises assorted threshold challenges to the Complaint. Defendants offer that all of the claims against them stem from the Lindseys' and Rahschulte's allegations that they were overcharged for local government premium taxes, which taxes arguably included undisclosed and improper collection fees. They note the exhibits reflect that Plaintiffs were charged the premium tax rates enacted by Falmouth and Florence, the local governments within whose boundaries Plaintiffs admit they reside, and the face of the exhibits evidence that no collection fees were charged.

Defendants, relying upon Mengel Co. v. Nashville Paper Products & Specialty Workers Union, No. 513, 221 F.2d 644 (6th Cir. 1995) and Wintermute v. Discover Card Services, 2008 WL 1772758 (W.D. Ky. Apr. 16, 2008), submit that because the exhibits to the Complaint directly contradict the Plaintiffs' allegations, the Complaint should be dismissed, as the exhibits control in such situations. The legal principle itself is not as straightforward as Defendants offer it to be, nor is its application. 1 The principle does not apply here, because there is no actual inconsistency between Plaintiffs' allegations and the exhibits. Plaintiffs' allegations are grounded in the alleged fact that the risk insured under each policy was not, in fact, located within the local government's taxing jurisdiction. Plaintiffs also maintain that the tax that was imposed could include an *undisclosed* collection fee.<sup>2</sup> The Court agrees that, accepting Plaintiffs' allegations as true and absent further discovery, the Court is not obligated to accept movant's representation that the charge as listed on the premium sheet is an accurate charge for local government premium taxes owed and that it does not include an undisclosed collection fee. Neither will the Court at this stage engage in an protracted legal analysis of the isolated issue of how the purported "plain words" of K.R.S. § 91A.080, which provides for a collection fee, should be interpreted.

The contradiction between an allegation of the complaint and an attached letter exhibit at issue in *Wintermute* was more obvious, with the letter exhibit contradicting ownership status of plaintiff's credit card account as alleged in her complaint. Moreover, *Wintermute* cites

to a Seventh Circuit decision, Northern Indiana Gun & Outdoor Shows, Inc. v. City of South Bend, 163 F.3d 449, 454 (7th Cir. 1998). The court in Northern Indiana Gun stressed caution when reviewing the content of attached exhibits for purposes of resolving purported conflicts with allegations of a complaint. While a document "will be read to evidence what it incontestably shows," the document itself "does not, however, establish the truth of these unilateral statements" and that "care not to overemphasize their importance" must be taken. Northern Indiana Gun, 163 F.3d at 455. Review of the exhibits here should be based upon considerations of context given the communications between the parties overall, see id. at 455, along with questions of evidentiary credibility and weight, all of which surpass what are appropriate considerations for this court on a motion to dismiss. See Jones v. City of Cincinnati, 521 F.3d 555, 561 (6th Cir. 2008).

- Plaintiffs acknowledge in their Response that later dismissal of their allegations relating to the imposition of an undisclosed collection fee may be appropriate, if discovery confirms that no such fee was, in fact, a part of any taxes charged to Plaintiffs.
- \*2 In addition to this general argument for dismissal, Defendants raise particularized arguments to the various counts of Plaintiffs' Complaint. Defendants pose that Counts I, II, IV, and V are each based upon the allegation that some misrepresentation was made to Plaintiffs by Defendants. They submit that the claims lack merit and should be dismissed at this initial pleading stage because the exhibits clearly show the amount of premium taxes imposed in accordance with each local government's tax requirement and, therefore, there can be no misrepresentation despite Plaintiffs' allegations to the contrary. Again, this is an oversimplification of the allegations and what Plaintiffs maintain constitutes the misrepresentation; i.e., the Defendants' failure to impose premium taxes based upon the location of the insured risk. The factual inquires surrounding such, and the extent to which those facts satisfy the legal elements for Plaintiffs' asserted theories of liability, survive Defendants' motion attack. Additionally, whether, as a matter of law, Plaintiffs are charged with knowledge of premium tax information stated on their premium statement based upon Kentucky's general legal rule that insureds are charged with knowledge of their policy provisions remains for another day, as adjudication of Plaintiffs' legal theories in a vacuum, prior to fact discovery, is inappropriate.

Defendants also seek dismissal of Count V, negligent misrepresentation, on grounds that Kentucky law limits claims for the tort of negligent misrepresentation to "business transactions." Presnell Constr. Managers, Inc. v. EH Constr., LLC, 134 S.W.2d 575, 581 (Ky. 2004). Relying upon Kentucky Farm Bureau Mutual Insurance Co. v. Blevins, 268 S.W.3d 368, 373 (Ky. Ct. App. 2008), Defendants suggest that because Plaintiffs are homeowners, their claims against Defendants do not arise from "business transactions." However, the parameters of what constitutes a business transaction for purposes of the tort and Restatement (Second) of Torts § 552 is not as clear cut as Defendants suggest that it is. Blevins involved a sale of residential real estate between two sets of homeowners. *Id.* at 373. In adopting § 552 and recognizing the tort of negligent misrepresentation, the Kentucky Supreme Court in *Presnell* cited favorably to a prior appellate decision, Seigle v. Jasper, 867 S.W.2d 476 (Ky. Ct. App. 1993), wherein that court permitted a claim for negligent misrepresentation as consistent with § 552 in circumstances where private individuals purchasing real estate asserted they relied upon negligent misrepresentation by their lending bank's attorney examining the title. Thus, for purposes of their Motion to Dismiss, the Court cannot summarily conclude that Plaintiffs' negligent misrepresentation claim fails to state a claim as a matter of law.

Defendants also protest that Count III, premised upon asserting a private right of action pursuant to K.R.S. § 446.070 based upon an alleged violation of K.R.S. § 304.12-190, the Illegal Dealing in Premiums statute, also fails to state a claim against them. While acknowledging in their Reply that the Court examined this contention in detail in adjudicating the threshold motions in *Kendrick, et al. v. Standard Fire Insurance Co., et al.*, Covington Division Case No. 06-141, and *Nichols, et al. v. Progressive Direct Insurance Co., et al.*, Covington Division Case No. 06-146, Defendants nevertheless maintain they offer additional authorities and argument not offered by the defendants there, which compel the conclusion that a private claim in court for alleged violation of the statute is not available to Plaintiffs.

Defendants rely upon *Grzyb v. Evans*, 700 S.W.2d 399 (Ky. 1985) for two contentions – that when the statute provides for both the unlawful act and the remedy for aggrieved parties, K.R.S. § 446.070 is not available to assert a cause of action for violation of a separate statute, and that in certain instances such as this case the sole statutory remedy may be that of an administrative action. Defendants contend that under *Grzyb* and cases like *Thompson v. Breeding*, 351 F.3d 732 (6th Cir. 2003), parties can be restricted to an administrative complaint avenue only, and that such is the

case here. They submit that Plaintiffs are restricted to the administrative remedy available under the Insurance Code, which remedy can include civil penalties imposed against the insurer by the executive director, with the director also having the authority under other provisions of the Insurance Code to require restitution as part of his power to issue final orders.

\*3 Defendants' offer of additional authorities and argument does not change the Court's prior analysis of this issue. Defendants overstate *Grzyb's* application to the circumstances here. *Grzyb* foreclosed a common law wrongful discharge claim where the statute that underpinned the public policy exception for the purported wrongful discharge claim, K.R.S. § 344.040, has its own remedial scheme as provided by Chapter 344's provision for filing a complaint with the Kentucky Commission on Human Rights. Defendants fail to point out that K.R.S. § 344.450 also specifies that a civil cause of action in court is permitted to recover the actual damages sustained, costs of the suit, and a reasonable attorney's fee. And in *Breeding*, the auctioneers' statute at issue expressly provided for the details of an administrative avenue and an award of monetary damages to an aggrieved party.

Defendants' reference to the additional case law and statutory provisions of the Insurance Code in advancing reconsideration to reject a private cause of action based upon K.R.S. § 446.070 are unpersuasive. These and the other authorities they rely upon are far more detailed in their declaration of the unlawful act and the civil remedy available than is Defendants' strained efforts to equate the imposition of "civil penalties" upon an insurer to that of "civil remedies" to an aggrieved party, or their reference to general provisions within the extensive Insurance Code that combined would permit the executive director to order "restitution" in some final order. This fails to satisfy the standard of both declaring the unlawful act and specifying the civil remedy available to the aggrieved party such that a private right of action under K.R.S. § 446.070 should be precluded. K.R.S. § 304.12-190 provides no remedy for Plaintiffs as aggrieved parties and so, as *Breeding* notes, in such instances application of K.R.S. § 446.070 is consistent with Kentucky's rule of statutory construction that "as between legislation of a broad and general nature on the one hand, and legislation dealing minutely with a specific matter on the other hand – the specific shall prevail over the general." Breeding, 351 F.3d at 737 (quoting City of Bowling Green v. Bd. of Educ., 443 S.W.2d 243, 247 (Ky. 1969)).

For these reasons, Defendants' Motion to Dismiss (Doc. #19) will be denied.

# Motion to Dismiss "Affiliated Companies"

Defendants have also filed a Motion to Dismiss the "Affiliated Companies" for lack of subject-matter jurisdiction. (Doc. # 22). Plaintiffs' Complaint seeks a defendant class comprised of:

Any company affiliated with American Security Insurance Company, licensed to do business and doing or having done business in the Commonwealth of Kentucky, which between June 14, 2001 and the date the Court signs an Order certifying the Defendant Class, issued a collective total of at least two hundred (200) policies insuring risks located in the Commonwealth of Kentucky.

Defendants argue that Plaintiffs lack standing to assert claims against the Affiliate Companies because they fail to allege any wrongs that were the result of the Affiliated Companies' conduct. The Court agrees.

Standing is a necessary requirement for justiciability. *Fallick v. Nationwide Mut. Ins. Co.*, 162 F.3d 410, 422 (6th Cir. 1998). It requires the plaintiff to demonstrate that "'a case and controversy' exists between himself and the defendant within the meaning of Article III." *Id. See also Thompson v. Bd. of Educ. of Romeo Comm. Sch.*, 709 F.2d 1200, 1204 (6th Cir. 1983) (noting that standing is required to bring suit, and Rule 23 does not change that requirement). In order to satisfy the standing requirement, Plaintiffs must allege: (1) an actual or imminent harm in fact; (2) the harm is fairly traceable to the defendants' alleged wrongful conduct; and (3) there is a substantial likelihood that court can grant Plaintiff's requested relief. *See Street v. PBS Lending, Corp.*, No. 01-2751 GV, 2002 WL 1797773, at \*12 (W.D. Tenn. July 31, 2002).

Although Plaintiffs argue that a decision on this motion is premature, the Court disagrees. Plaintiffs argue that based on the Supreme Court's decision in *Ortiz v. Fibreboard Corp.*, 527 U.S. 815 (1999), this Court must wait to consider whether the Plaintiffs have standing against the Defendants until after the class certification issue is decided because class certification issues are "logically antecedent" to standing issues. However, the facts of the *Ortiz* case are very different from those at hand, and the Supreme Court recognized in that case that ordinarily a court must be sure of its own jurisdiction before addressing the merits of a matter. Accordingly, this Court can find no reason to postpone addressing

the standing issue until the class certification issue is decided, especially when no such motion is presently before the Court. *See Street v. PBS Lending Corp.*, No. 01-2751 GV, 2002 WL 1797773, at \*13 (W.D. Tenn. July 31, 2002).

\*4 A plaintiff cannot represent those having a cause of action against defendants when the plaintiff has no cause of action against each defendant, even where the alleged harm is identical. *See Thompson*, 709 F.2d at 1204. However, there are two exceptions to this general rule. *Id.* The first occurs in situations where the injuries result from a conspiracy or concerted scheme between the defendants. *Id.* at 1204-05. The second occurs where the defendants are "juridically related in a manner that suggests a single resolution of the dispute would be expeditious." *Id.* at 1205.

Defendants correctly argue that Plaintiffs cannot satisfy the standing requirement because Plaintiffs specifically allege harm which stems from only two named entities, not the Affiliate Companies. Specifically, Plaintiffs Lindsey claim that they were harmed by the alleged unlawful collection of a premium tax by American Security, and Plaintiff Rahschulte alleges harm by the unlawful collection of a premium tax by American Bankers. Neither Plaintiff alleges that they were harmed by an Affiliate Company, and thus any harm alleged is not fairly traceable to the Affiliate Companies. Therefore, Plaintiffs have failed to allege standing as to the Affiliate Companies.

Furthermore, Plaintiffs' reliance on the "juridically related" exception is misplaced. Plaintiffs allege that the common ownership of American Security, American Bankers, and the Affiliate Companies, as well as the uniform common practice of improperly calculating, collecting, and remitting premium taxes places this situation within the "juridically related" exception. However, the "juridically related" exception is limited to very specific instances. See Thompson, 709 F.2d at 1205 (noting that this is exception most often occurs in certain factual situations). These situations include "where all members of the defendant class are officials of a single state and are charged with enforcing or uniformly acting in accordance with a state statute, or common rule or practice of state-wide application, which is alleged to be unconstitutional." The defendants in this case are not members of a state nor are they acting upon a single statute or common rule. While Plaintiffs allege a common practice, they failed to allege a conspiracy between the companies, which would demonstrate that a common rule was in place. Accordingly, what Plaintiffs have alleged are two legally separate companies with the same allegedly unlawful policy. However, the determination of the existence of an alleged policy and the question of harm are based on the specific facts of each situation, which are very different. *See id.* (noting that a separate determination as to the separate policies and whether the harm occurred prevented application of the "juridically related" exception).

Additionally, Plaintiffs allege that the alleged common conduct creates enough of a link for Rule 23 purposes. However, this argument is irrelevant, because the issue is standing, not class certification under Rule 23. As specifically stated by the Sixth Circuit in *Thompson*, a plaintiff must have standing against each defendant, and Rule 23 does not alter this requirement. *See Thompson*, 709 F.2d at 1204; *Fallick*, 162 F.3d at 423 (noting that a potential class representative must have individual standing against each defendant and that he cannot obtain such standing simply by bringing the class action).

For these reasons, Defendants' Motion to Dismiss the Affiliated Companies (Doc. #22) will be granted.

# Motion to Sever

\*5 On a related matter, Defendants have also filed a Motion to Sever Plaintiff Rahschulte pursuant to Rule 21. (Doc. #21). Defendants argue that Plaintiff Rahschulte was improperly joined and should thus be severed from the matter because he does not satisfy the transactional relatedness and commonality requirements of Rule 20(a).

Federal Civil Rule 20 states that plaintiffs may be joined if: (1) they assert a right to relief which arises out of the same transaction, occurrence, or series of transactions or occurrences; and (2) a question of law or fact common to all plaintiffs exists. See Fed. R. Civ. P. 20(a). It is well settled that both prongs must be satisfied in order for proper joinder. See Michaels Bldg. Co. v. Ameritrust Co., 848 F.2d 674, 682 (6th Cir. 1988). Furthermore, trial courts have substantial discretion in determining whether to sever claims. Id.

In the case at bar, Plaintiff Rahschulte cannot satisfy either prong, and therefore, he should be severed from the action. First, Plaintiff Rahschulte cannot satisfy the transactional relatedness prong because he cannot assert a claim arising out of the same transaction or occurrence. *See Abdelkarim v. Gonzales*, No. 06-14436, 2007 WL 1284924, at \*4 (E.D. Mich. April 30, 2007) (noting that the "same transaction" prong relates to the similiarity of the facts underlying the

claim). The facts underlying each Plaintiff's claim in this case are completely different. There were entirely separate transactions, the plaintiffs themselves are not related, and the claims are against two legally independent entities. Furthermore, the allegedly unlawful actions occurred at different times, different locations, and under different circumstances. Accordingly, the right to relief asserted by Plaintiff Rahschulte does not arise out of the same transaction because the underlying facts are entirely different, and his claim should be severed.

Additionally, Plaintiff Rahschulte's claim fails to satisfy the commonality prong because no common question of law or fact applies to all plaintiffs. As discussed above, the underlying facts to each Plaintiff's claim are very different, and thus there is clearly no common question of fact. Furthermore, although Plaintiffs argue that the same alleged harm exists, because the underlying facts are different, this does not satisfy the commonality prong of the joinder analysis. See Nassau County Ass'n of Ins. Agents, Inc. v. Aetna Life & Casualty Co., 497 F.2d 1151, 1154 (2d Cir. 1974) (finding joinder of defendants improper, even though the alleged wrongs were the same); Bridgeport Music, Inc. v. 11C Music, 202 F.R.D. 229, 232 (M.D. Tenn. 2001) (determining that alleging only the same harm, when the underlying facts are different, does not satisfy the standard for proper joinder). Plaintiffs' reliance on Independent Liberty Life Insurance is misplaced. In that case, there was only one plaintiff and several defendants, and the court addressed the propriety of joining defendants and stated that even though not each count applied to all defendants, the fact that the plaintiff could assert common counts against each defendant satisfied the joinder analysis. Independent Liberty Ins. Co. v. Fiduciary & General Corp., 91 F.R.D. 535, 538 (W.D. Mich. 1981). That is not the case here. The Lindseys can only assert a claim against American Securities, and Rahschmulte can only assert a claim against American Bankers. There is no commonality amongst the parties.

\*6 Finally, even the alleged presence of a corporate parent does not satisfy the commonality requirement because there is no evidence of a common scheme. Defendants operate separately and individually, and with the difference of facts underlying the claims, joinder is simply improper. See Grayson v. K-Mart Corp., 849 F. Supp. 785, 786-90 (N.D. Georgia 1994) (deciding that joinder was improper in an employment discrimination action because the facts of each circumstance, regardless of any alleged policy or corporate parent, must be considered, thus destroying commonality).

For these reasons, Defendants' Motion to Sever (Doc. # 21) will be granted, with both Rahschulte and American Bankers being severed from this action.<sup>4</sup>

Although Defendants' motion only petitions to sever Plaintiff Rahschulte, based on the reasoning of the opinion and the fact that the Lindseys have no claim against American Bankers, it only makes sense to sever both Plaintiff Rahschulte and Defendant American Bankers. Accordingly, both are severed and their action shall continue separately.

Therefore, **IT IS ORDERED** as follows:

- (1) Defendants' Motion to Dismiss (Doc. #19) is hereby **denied.**
- (2) Defendants' Motion to Dismiss Affiliated Companies (Doc. #22) is hereby **granted.**
- (3) Defendants' Motion to Sever (Doc. #21) is hereby granted. The claim of Plaintiff William R. Rahschulte, individually on behalf of himself and a class of similarly situated persons, against Defendant American Bankers Insurance Co. of Florida is hereby severed from the pending action filed by Belinda and Sheldon Lindsey, together on behalf of themselves and a class of similarly situated persons, against American Security Insurance Company. The Lindseys' cause of action shall continue under Covington Civil Action No. 08-cv-126, and Rahschulte and American Bankers shall be stricken as named parties herein. A separate civil action shall be opened identifying William R. Rahschulte as the named Plaintiff therein, on behalf of himself and a class of similarly situated persons, against American Bankers Insurance Co. of Florida. The Clerk shall file therein a copy of the Complaint filed by Plaintiff Rahschulte in case number 08-cv-126, along with a copy of this Memorandum Order, and Plaintiff shall have thirty (30) days therefrom within which to tender the requisite civil action filing fee.
- (4) The Defendant in this proceeding, American Security Insurance Company, and the Defendant in the severed proceeding, American Bankers Insurance Co. of Florida, shall each file its Answer not later than **April 15, 2010.**

# **All Citations**

Slip Copy, 2010 WL 11640212

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Document 1451-1 PageID: 33226

# **Tab 20**

Case 1:19-md-02875-RMB-SAK Document 1451-1 Loreto V. Procter & Gamble Co., 515 Fed. Appx. 576 (2013) Page 1D: 33227

KeyCite Yellow Flag - Negative Treatment

Distinguished by Aleisa v. GOJO Industries, Inc., N.D.Ohio, May 11, 2021

515 Fed.Appx. 576

This case was not selected for
publication in the Federal Reporter.

Not for Publication in West's Federal Reporter.

See Fed. Rule of Appellate Procedure 32.1
generally governing citation of judicial decisions
issued on or after Jan. 1, 2007. See also
Sixth Circuit Rule 28. (Find CTA6 Rule 28)

Richard LORETO, on behalf of himself and others similarly situated; Larry Buffa, on behalf of himself and others similarly situated, Plaintiffs—Appellants,

United States Court of Appeals, Sixth Circuit.

The PROCTER & GAMBLE COMPANY, Defendant—Appellee.

No. 10–4274. | Feb. 22, 2013.

# **Synopsis**

**Background:** Consumers brought putative class action against cold medicine manufacturer, alleging violations of state law including the Ohio Consumer sales Practices Act (OCSPA), Ohio's Deceptive Trade Practices Act (ODTPA), and New Jersey Consumer Protection Act (NJCPA). Manufacturer filed motion to dismiss. The United States District Court for the Southern District of Ohio, Timothy s. Black, J., 737 F.Supp.2d 909, granted motion. Consumers appealed.

**Holdings:** The Court of Appeals, Griffin, Circuit Judge, held that:

- [1] under Ohio choice of law rules, New Jersey law applied,
- [2] allegations that manufacturer omitted telling consumers that labeling of its products containing vitamin C did not comply with the Food, Drug and Cosmetics Act's (FDCA)

requirements attempted to assert a private right of action under the FDCA;

- [3] allegation that cold medicine manufacturer made false or misleading representations about the efficacy of vitamin C was not preempted by FDCA; and
- [4] allegations were sufficient to plead ascertainable loss under NJCPA.

Affirmed in part and reversed in part.

West Headnotes (4)

# [1] Antitrust and Trade Regulation • What law governs; territorial limitations

Under Ohio choice of law rules, New Jersey law applied in consumer protection action, where New Jersey was plaintiffs' state of residence, the state where they purchased the products, and was "place of injury" here.

- 3 Cases that cite this headnote
- [2] Action Statutory rights of action

Antitrust and Trade

Regulation Preemption

**Health** ← Judicial review or intervention **States** ← Trade Regulation; Monopolies

Consumers' claim, under New Jersey Consumer Fraud Act (NJCFA), that cold medicine manufacturer omitted telling them that labeling of its products containing vitamin C was illegal because it did not comply with Food, Drug and Cosmetics Act's (FDCA) requirements was impliedly preempted; consumers' theory of liability depended entirely upon violation of FDCA, which provided no private enforcement mechanism. Federal Food, Drug, and Cosmetic Act, § 1 et seq., 21 U.S.C.A. § 301 et seq.; N.J.S.A. 56:8–19.

26 Cases that cite this headnote

# [3] Antitrust and Trade

**Regulation**  $\hookrightarrow$  Preemption

**States**  $\leftarrow$  Trade Regulation; Monopolies

Consumers' allegation that cold medicine manufacturer made false or misleading representations about the efficacy of vitamin C in its products was not an attempt to assert a private right of action under the Food, Drug and Cosmetics Act (FDCA), and thus consumers' contention that manufacturer violated the New Jersey Consumer Protection Act (NJCPA) was not preempted by the FDCA, where such theory relied solely on traditional state tort law predating the FDCA, and would exist in the absence of the Act. Federal Food, Drug, and Cosmetic Act, § 1 et seq., 21 U.S.C.A. § 301 et seq.; N.J.S.A. 56:8–19.

30 Cases that cite this headnote

# [4] Antitrust and Trade Regulation 🌦 Labeling and packaging

Consumers' allegation that they purchased certain cold medicines based on manufacturer's misleading advertisements as to efficacy of vitamin C in the medicine, rather than cheaper alternatives, were sufficient to plead ascertainable loss, as required for consumers' putative class action under the New Jersey Consumer Protection Act (NJCPA) against manufacturer; "quantifiable or measurable" loss was the difference in price between manufacturer's product and a lower-priced competing product. N.J.S.A. 56:8–19.

3 Cases that cite this headnote

## **West Codenotes**

# **Limited on Preemption Grounds**

N.J.S.A. 56:8-19.

\*577 On Appeal from the United States District Court for the Southern District of Ohio.

BEFORE: GRIFFIN and KETHLEDGE, Circuit Judges; and THAPAR, District Judge.\*

The Honorable Amul R. Thapar, United States District Judge for the Eastern District of Kentucky, sitting by designation.

# **Opinion**

GRIFFIN, Circuit Judge.

\*\*1 Plaintiffs Richard Loreto and Larry Buffa appeal the district court's dismissal of their claims against Procter & Gamble for violation of various consumer-protection statutes. For the following reasons, we affirm in part and reverse in part.

I.

This proposed class action involves the charge that Procter & Gamble was unjustly enriched and violated the consumer-protection laws of all fifty States when it sold and marketed two new products in 2009: DayQuil Plus Vitamin C and NyQuil Plus Vitamin C. According to plaintiffs, the company sought to exploit the commonly held, yet allegedly unfounded, belief that Vitamin C is effective for treating cold symptoms by adding the vitamin to its DayQuil and NyQuil products and using the following statements in its advertisements:

Combining the powerful multi-symptom relief of DayQuil with more than 150% of the recommended value of vitamin C.

\*578 VICKS NyQuil Cold & Flu Symptom Relief Plus Vitamin C provides multi-symptom cold and flu relief so you can get the sleep you need to enjoy an even sweeter tomorrow. Plus, you'll also replenish your body with 150% of the daily value of vitamin C.

Vitamin C: It won't cure a cold, but vitamin C can help blunt its effects. Aim for 500 mg a day.

Fighting Cold and Flu Season.... Don't forget to take your daily vitamins. Consider taking extra vitamin C, vitamin A, and zinc, all of which may help you.

Plaintiffs purchased the products over competing ones in part because of these statements. They allege that no scientific evidence supports the claim that Vitamin C can alleviate cold symptoms, and that, but for Procter & Gamble's false or misleading statements to the contrary, plaintiffs would have purchased a lower-priced competing product instead. Plaintiffs seek a refund of the purchase price. They also request class treatment. Exercising original jurisdiction under the Class Action Fairness Act of 2005, 28 U.S.C. § 1332(d), the district court dismissed all of plaintiffs' claims. Plaintiffs timely appealed.

II.

We first address which state's law applies. Ohio is the [1] forum state, so we apply its choice-of-law rules. Klaxon Co. v. Stentor Elec. Mfg. Co., 313 U.S. 487, 496, 61 S.Ct. 1020, 85 L.Ed. 1477 (1941). Under Ohio's rules, "the place of the injury controls in a consumer-protection lawsuit, requiring application of the home-state law of each potential class member." Pilgrim v. Universal Health Card, LLC, 660 F.3d 943, 947 (6th Cir.2011) (applying Morgan v. Biro Mfg. Co., 15 Ohio St.3d 339, 474 N.E.2d 286 (1984)). New Jersey, plaintiffs' state of residence and the state where they purchased the products, was the "place of injury" here, so its law applies. See id.

Plaintiffs respond that Ohio law should apply because the advertising campaign they challenge emanated from Procter & Gamble's Ohio headquarters. They rely on two decisions —Parker v. Berkley Premium Nutraceuticals, Inc., 2005 Ohio Misc. LEXIS 605 (Ohio C.P.2005), and Brown v. Market Development, Inc., 41 Ohio Misc. 57, 322 N.E.2d 367 (Ohio C.P.1974). But we declined to follow those very decisions in Pilgrim, and Pilgrim is indistinguishable. See Pilgrim, 660 F.3d at 947. The district court correctly dismissed plaintiffs' claims under Ohio law.

III.

\*\*2 That leaves plaintiffs' claim under New Jersey's Consumer Fraud Act, which the district court dismissed under Federal Rule of Civil Procedure 12(b)(6). We review that decision de novo. See Roberts v. Hamer, 655 F.3d 578, 581 (6th Cir.2011).

Plaintiffs abandoned their unjust-enrichment claim by not addressing it in their opening brief. See Music v.

Arrowood Indem. Co., 632 F.3d 284, 286 n. 1 (6th Cir.2011).

The district court offered alternative reasons for dismissing plaintiffs' New Jersey claim. It determined first that the claim was preempted by the Federal Food, Drug, and Cosmetic Act (the "FDCA" or "Act"). It also ruled that the claim was not cognizable under New Jersey law.

A.

We first consider Procter & Gamble's preemption argument. "The FDCA leaves no doubt that it is the Federal Government rather than private litigants who [is] authorized to file suit for noncompliance with" its substantive provisions. \*579 Buckman Co. v. Plaintiffs' Legal Comm., 531 U.S. 341, 349 n. 4, 121 S.Ct. 1012, 148 L.Ed.2d 854 (2001); see Bailey v. Johnson, 48 F.3d 965, 966 (6th Cir. 1995) (recognizing that the FDCA creates no express or implied private cause of action). The statute's public enforcement mechanism is thwarted if savvy plaintiffs can label as arising under a state law for which there exists a private enforcement mechanism a claim that in substance seeks to enforce the FDCA. Under principles of "implied preemption," therefore, private litigants may not "bring a state-law claim against a defendant when the statelaw claim is in substance (even if not in form) a claim for violating the FDCA [.]" Riley v. Cordis Corp., 625 F.Supp.2d 769, 777 (D.Minn.2009) (citing Buckman Co., 531 U.S. at 352-53, 121 S.Ct. 1012); see In re Epogen & Aranesp Off-Label Mktg. & Sales Practices Litig., 590 F.Supp.2d 1282, 1290-91 (C.D.Cal.2008) ("[P]laintiffs may not use other federal statutes or state unfair competition laws as a vehicle to bring a private cause of action that is based on violations of the FDCA.").

The question, then, is how to determine whether a claim formally asserted under state law is in substance one seeking to enforce the FDCA. The Supreme Court supplied the test in Buckman: If the claim would not exist in the absence of the FDCA, it is impliedly preempted. 531 U.S. at 353, 121 S.Ct. 1012. In other words:

[T]he conduct on which the claim is premised must be the type of conduct that would traditionally give rise to liability under state law—and that would give rise to liability under state law even if the FDCA had never been enacted. If the defendant's conduct is not of this type, then the plaintiff is effectively suing for a violation of the FDCA (no matter how the plaintiff labels the claim), and the plaintiff's claim is thus impliedly preempted under Buckman.

Riley, 625 F.Supp.2d at 777. In Buckman, for example, the Court deemed preempted a state tort claim that the defendant defrauded the FDA in the course of obtaining approval for its medical devices and that, as a result, the devices improperly obtained market clearance and were later used to the plaintiffs' detriment. The claims, the Court held, did not rely on "traditional state tort law which had predated" the FDCA, for the Act's existence was "a critical element" of the plaintiffs' case. 531 U.S. at 353, 121 S.Ct. 1012. In other words, were it not for the federal regulatory scheme the FDCA created, there would have been no fraud that could support the tort claim.

- \*\*3 In this case, plaintiffs have asserted claims under state consumer-protection laws based upon two different theories, only one of which is impliedly preempted by the FDCA.
- [2] First, the preempted theory. Plaintiffs allege that Procter & Gamble omitted telling consumers that its products were "illegal," and had plaintiffs known it, they wouldn't have purchased the products. The products were illegal, plaintiffs maintain, because their labeling did not comply with the FDCA's requirements. This theory of liability depends entirely upon an FDCA violation—i.e., the only reason Procter & Gamble's products were allegedly "illegal" was because they failed to comply with FDCA labeling requirements. The theory is impliedly preempted by federal law.
- [3] Apart from this clearly preempted theory, plaintiffs also allege that Procter & Gamble violated state law when it represented to the public that taking Vitamin C can blunt the effects of a cold, a statement plaintiffs contend is false or misleading. These statements allegedly induced plaintiffs to purchase the advertised products \*580 instead of a lowerpriced competitor's product not containing Vitamin C. This theory relies solely on traditional state tort law predating the FDCA, and would exist in the absence of the Act. *Buckman*, 531 U.S. at 353, 121 S.Ct. 1012. This claim is not preempted.

To be sure, the complaint does include extensive reference to a warning letter the FDA issued to Procter & Gamble concerning its products, which might suggest plaintiffs' second theory also depends upon the FDCA. That letter warns that FDA regulations do not permit combining Vitamin C with any of the active ingredients contained in DayQuil and NyQuil in part because the evidence is "insufficient to classify vitamin C as safe and effective" for over-the-counter use. Even though the FDA has apparently concluded that Vitamin C has not been proven effective in cold treatment, plaintiffs' claim does not depend upon this determination and would logically exist even in its absence. Cf. In re Epogen, 590 F.Supp.2d at 1291 ("[S]ome false statements made in connection with prescription drug marketing are actionable under state or federal law, even if their truth may be generally within the purview of the FDA." (citation and internal quotation marks omitted)).

B.

The district court alternatively held that plaintiffs failed to state a claim under New Jersey's Consumer Fraud Act because they did not plausibly allege an "ascertainable loss." N.J.Rev.Stat. § 56:8–19; see Bosland v. Warnock Dodge, Inc., 197 N.J. 543, 964 A.2d 741, 749 (2009) (an ascertainable loss is "without any question" an element of a private plaintiff's prima facie case under the Act).

"Ascertainable loss" is not defined in the statute, and "[t]here is little that illuminates the precise meaning that the Legislature intended in respect of the term." Thiedemann v. Mercedes-Benz USA, LLC, 183 N.J. 234, 872 A.2d 783, 792 (2005). Recognizing this analytical void, the New Jersey Supreme Court offered guidance in Thiedemann. In order to reach a jury, the court instructed, "a private plaintiff must produce evidence from which a factfinder could find or infer that the plaintiff suffered an actual loss." Id. (emphasis added). An "out-of-pocket loss" will do. Id. Moreover, a plaintiff's burden at summary judgment is to put forth "evidence of loss that is not hypothetical or illusory"; he must present the evidence "with some certainty demonstrating that it is capable of calculation." Id.; see also Bosland, 964 A.2d at 749–50 (an ascertainable loss is "quantifiable or measurable," not "merely theoretical").

\*\*4 [4] Here, plaintiffs allege that they suffered an outof-pocket loss when they purchased DayQuil or NyQuil Plus Vitamin C instead of a lower-priced competing cold medicine that did not contain the vitamin. The district court found this loss insufficient as a matter of law. In its view, plaintiffs suffered no loss in the absence of any allegation that the product failed to treat their colds, one plaintiffs never made. In other words, plaintiffs received precisely what they paid for—an effective cold remedy.

The district court erred by ignoring the allegation that plaintiffs would have purchased a lower-priced cold remedy (thus saving money) were it not for Procter & Gamble's alleged misrepresentations. The "quantifiable or measurable" loss in this case is the difference in price between Procter & Gamble's product and a lower-priced competing product.<sup>2</sup> The products' \*581 overall effectiveness in treating plaintiffs' cold symptoms does not undercut a showing of ascertainable loss. Cf. Desiano v. Warner-Lambert Co., 326 F.3d 339, 349-50 (2d Cir.2003) (finding loss sufficient to support a similar claim under New Jersey's Consumer Fraud Act, explaining that the plaintiffs' claim was "unaffected" by whether anyone was physically injured by the defendant's drug; the fact that the plaintiffs purchased the defendant's product instead of a cheaper alternative was sufficient to demonstrate loss); In re Bayer Corp. Combination Aspirin Prods. Mktg. & Sales Practices Litig., 701 F.Supp.2d 356, 380-81 (E.D.N.Y.2010) (allowing a similar claim under New Jersey law to proceed, noting that the plaintiffs' inability to point to any physical injuries from the product was "immaterial"; economic loss existed where, as here, the plaintiffs alleged that the defendant's misrepresentations were the very reason plaintiffs purchased the product); In re Bextra & Celebrex Mktg., Sales Practices & Prod. Liability Litig., No. MDL 05-01699, 2007 WL 2028408, at \*5-6 (N.D.Cal. July 10, 2007) (finding economic loss where the plaintiffs alleged "that physicians prescribed Celebrex and insurers paid for it precisely because defendants falsely marketed it as having fewer gastrointestinal symptoms than the [cheaper] available over-the-counter NSAIDs"; "in other words, plaintiffs could have and would have received exactly the same relief at a much lower cost but for defendants' deception").

Although plaintiffs seek a refund of the full purchase price, even if they prevail, they are not entitled to one. Their claim is that they would have purchased a lowerpriced product not containing Vitamin C but for the misrepresentation, not that they would have foregone purchasing any product.

IV.

Procter & Gamble offers alternative grounds for affirming. See Harchar v. United States (In re Harchar), 694 F.3d 639, 644 (6th Cir.2012) ("We may affirm the district court's dismissal of a plaintiff's claim on any preserved ground, including a ground not relied upon by the district court.").

First, Procter & Gamble contends that plaintiffs lack Article III standing because they can demonstrate no "injury in fact." See Lujan v. Defenders of Wildlife, 504 U.S. 555, 560, 112 S.Ct. 2130, 119 L.Ed.2d 351 (1992). This argument simply repackages the company's argument regarding ascertainable loss. Plaintiffs' allegation that they suffered a monetary loss by paying more for a cold remedy because of the company's misrepresentation establishes a cognizable injury.

\*\*5 The cases Procter & Gamble relies upon are inapposite. See Rivera v. Wyeth-Ayerst Labs., 283 F.3d 315, 319-21 (5th Cir.2002) (finding no legal injury where the plaintiffs purchased a drug that failed to warn of possible sideeffects yet performed as expected; however, the plaintiffs did not allege that they would have purchased a lowerpriced alternative but for the failure to warn); Medlev v. Johnson & Johnson Consumer Cos., No. 10-cv-02291, 2011 WL 159674, at \*2 & n. 2 (D.N.J. Jan. 18, 2011) (holding that there was no injury where parents who purchased baby shampoo used the product without adverse health effects and only later discovered that the product contained a potentially harmful chemical; however, the parents never alleged an economic injury from paying a premium for the product); Williams v. Purdue Pharma Co., 297 F.Supp.2d 171, 177-78 (D.D.C.2003) (finding no standing where the plaintiff suffered no physical injury from the drug, declining to recognize an economic injury based on the claim that the drug's price \*582 was inflated because of false advertising; however, the plaintiff never claimed he would have purchased a lower-priced alternative but for the advertising).

Second, Procter & Gamble contends that plaintiffs' claims fail because the four statements upon which they are basedset forth in section I above—are neither false nor plausibly misleading. We agree with respect to all but one statement: "Vitamin C: It won't cure a cold, but vitamin C can help blunt its effects."<sup>3</sup> It is plausible that plaintiffs could prove that Vitamin C either has no effect on cold symptoms or has such a marginal effect that advertising its ability to blunt cold symptoms creates a "capacity to mislead" the average consumer. Union Ink Co. v. AT&T Corp., 352 N.J.Super. 617, 801 A.2d 361, 379 (N.J.Super.Ct.App.Div.2002); see also Miller v. Am. Family Publishers, 284 N.J.Super. 67, 663 A.2d 643, 653-54 (N.J.Super.Ct.Ch.Div.1995) ("[A] claim of literal truth will not constitute a defense to a charge that the overall impression created by an advertisement is misleading and deceptive to an ordinary reader."). The company responds that the statement, "taken in its entirety, clearly and expressly disclaims the usefulness of vitamin C as a cure for colds." (Emphasis added.) True enough, but the statement goes beyond disclaiming the vitamin's ability to cure a cold; it claims the vitamin can blunt the effects of a cold, a claim plaintiffs have plausibly alleged is false or misleading.

3 The complaint states no basis upon which to conclude that the three remaining statements are false, and any allegation that they are misleading to average consumers is implausible. Although the statement "Consider taking extra vitamin C, vitamin A, and zinc, all of which may help you" presents a somewhat closer question, we ultimately find that the statement cannot be misleading because it does not state that the listed products will do anything, only that they might. See New Jersey Citizen Action v. Schering-Plough, 367 N.J.Super. 8, 842 A.2d 174, 177 (N.J.Super.App.Div.2008) (holding that, to be actionable under the New Jersey Consumer Fraud Act, allegedly misleading statements must be "statements of fact"); Wendling v. Pfizer, Inc., No. L-348-04, 2008 WL 833549, at \*3–5 (N.J.Super.App.Div. Mar. 31, 2008) (per curiam) (same).

V.

Finally, the district court dismissed plaintiffs' claims under the consumer-protection laws of the other forty-nine States because it found plaintiffs could state none of their own claims. Now that we have revived a portion of plaintiffs' New Jersey statutory claim, the district court's rationale no longer applies. In the ordinary case, we would reinstate the claims and allow the district court on remand to consider whether class treatment is appropriate. *See Glazer v. Chase Home Fin. LLC*, 704 F.3d 453, 458 n. 2 (6th Cir.2013). However, in view of our recent decision in *Pilgrim* that a federal district court in Ohio could not certify a nationwide class of members asserting consumer-protection claims under all fifty States given Ohio's choice-of-law rules and the material differences between the States' consumer-protection laws, 660 F.3d at 945, reinstating the claims would be futile. Therefore, we affirm the dismissal of these claims.

VI.

\*\*6 For these reasons, we reverse the portion of the judgment dismissing plaintiffs' claim under New Jersey's Consumer Fraud Act predicated on Procter & Gamble's statement in its advertising that Vitamin C "won't cure a cold, but ... can help blunt its effects." In all other respects, we affirm.

#### **All Citations**

515 Fed.Appx. 576, 2013 WL 645952

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# **Tab 21**

2020 WL 6047253 Only the Westlaw citation is currently available. United States District Court, N.D. California, San Jose Division.

# IN RE: MACBOOK KEYBOARD LITIGATION

Case No. 5:18-cv-02813-EJD | | | Signed 10/13/2020

# ORDER GRANTING MOTION TO DISMISS

Re: Dkt. No. 221

# EDWARD J. DAVILA, United States District Judge

\*1 Before the Court is Defendant Apple Inc.'s motion to dismiss Plaintiffs' Second Amended Consolidated Class Action Complaint ("SAC") pursuant to Federal Rule of Civil Procedure 12(b)(6). Dkt. No. 221 ("Motion"). Specifically, Apple seeks to dismiss Plaintiffs' claim for violation of the California Unfair Competition Law in its entirety, and Plaintiffs' remaining claims to the extent that they seek equitable relief, on the ground that Plaintiffs do not and cannot plead that they lack an adequate remedy at law. The Court took the matter under submission for decision without oral argument pursuant to Civil Local Rule 7-1(b). Having considered the arguments of the parties, the Court GRANTS Defendant's motion.

## I. Background

Plaintiffs are eleven consumers from California, Massachusetts, New York, Illinois, Florida, Washington, New Jersey, and Michigan. Second Amended Consolidated Class Action Complaint, Dkt. No. 219 ("SAC") ¶¶ 8-18. Plaintiffs bring this proposed class action against Defendant Apple, Inc. ("Apple" or "Defendant") on behalf of purchasers of allegedly defective MacBook laptops with butterfly keyboards.

Each Plaintiff alleges to have purchased a MacBook or MacBook Pro with the butterfly keyboard. *Id.* ¶¶ 25, 31, 39, 49, 56, 63, 71, 77, 85, 95, 103. Each one alleges to have made the purchase after being exposed to representations

on specific Apple websites that the butterfly is "more responsive." *Id.* ¶¶ 26, 32, 40, 50, 57, 64, 72, 78, 86, 96, 104. Plaintiffs allege that their keyboards failed within a year of purchase. Id. ¶¶ 27, 33, 41, 51, 58, 65, 73, 79, 87, 97, 105. Each Plaintiff alleges that he consulted with or complained to Apple about the faulty keyboards, but Apple failed to provide effective troubleshooting or repairs, an operable replacement laptop free of charge, or a refund. *Id.* ¶¶ 28-29, 36-37, 42-27, 52-54, 60-62, 66-69, 74-75, 80-83, 88-93, 98-101, 106-08. Plaintiffs all allege that after having their laptops repaired or replaced, the defect returned. Id. Several Plaintiffs allege that they were forced to spend money out of pocket for AppleCare service, insurance, or a new non-Apple laptop. Id. Plaintiffs allege that had they been aware of the keyboard defect, they would not have bought their computer or would have paid significantly less for it. Id. ¶¶ 30, 38, 48, 55, 62, 70, 76, 84, 94, 102, 109.

Plaintiffs assert claims on behalf of a proposed nationwide class and subclasses under California law and six other states' laws. In particular, Plaintiffs seek injunctive relief and restitution under California's Unfair Competition Law, Cal. Bus. & Prof. Code § 17200 et seq. ("UCL"). They further seek unspecified injunctive relief under the Consumers Legal Remedies Act, Cal. Civ. Code § 1750 et seq. ("CLRA") and equivalent state statutes. <sup>1</sup>

Plaintiffs' fifth through tenth claims for relief are brought under the Washington Consumer Protection Act, Wash. Rev. Code § 19.86.010, et seq. ("WCPA"), Florida Deceptive and Unfair Trade Practices Act, Fla. Stat. § 501.201, et seq. ("FDUTPA"), the Illinois Consumer Fraud and Deceptive Business Practices Act 815 Ill. Comp. Stat. Ann. 505/1, et seq. ("ICFA"), New Jersey Consumer Fraud Act, N.J. Stat. Ann. § 56:8-1 (West), et seq. ("NJCFA"), New York General Business Law § 349, N.Y. Gen. Bus. Law § 349, and the Michigan Consumer Protection Act, Mich. Comp. Laws § 445.901, et seq. ("MCPA").

# II. Legal Standard

\*2 Federal Rule of Civil Procedure 8(a) requires a plaintiff to plead each claim with sufficient specificity to "give the defendant fair notice of what the ... claim is and the grounds upon which it rests." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555, 127 S. Ct. 1955, 167 L. Ed. 2d 929 (2007) (internal quotations omitted). A complaint which falls short of the Rule 8(a) standard may be dismissed if it fails to state a claim upon which relief can be granted. Fed. R. Civ. P. 12(b)(6).

To survive a Rule 12(b)(6) motion to dismiss, the complaint "must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678, 129 S. Ct. 1937, 173 L. Ed. 2d 868 (2009) (quoting *Bell Atlantic Corp.*, 550 U.S. at 570). A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged. *Id.* Dismissal "is proper only where there is no cognizable legal theory or an absence of sufficient facts alleged to support a cognizable legal theory." *Navarro v. Block*, 250 F.3d 729, 732 (9th Cir. 2001).

### III. Discussion

Defendant seeks to dismiss all of Plaintiffs' claims for equitable relief on the ground that Plaintiffs do not and cannot plead that they lack an adequate remedy at law. Defendant's motion relies on the Ninth Circuit's recent decision in *Sonner* v. Premier Nutrition Corp., 971 F.3d 834, 843-44 (9th Cir. 2020). In that case, the Sonner similarly brought a diversity suit under California's UCL and CLRA. Following a lastminute amendment of her complaint before trial, plaintiff dropped her damages claim and sought only restitution and equitable relief. Id. at 838–39. The district court then granted a motion to dismiss, finding that Sonner could not proceed on her equitable claims for restitution in lieu of a claim for damages. Specifically, the district court concluded that claims brought under the UCL and CLRA remained subject to California's inadequate-remedy-at-law doctrine, and that Sonner failed to establish that she lacked an adequate legal remedy for the same past harm for which she sought equitable restitution.

On appeal, the Ninth Circuit affirmed on different grounds, relying on principles of federal common law rather than state law. The Ninth Circuit explained that while a state may authorize its courts to give equitable relief without the restriction that an adequate remedy at law be unavailable, the state law "cannot remove th[at] fetter[] from the federal courts." Id. at 843-44 (citing Guar. Tr. Co. of N.Y. v. York, 326 U.S. 99, 105–06, 65 S. Ct. 1464, 89 L. Ed. 2079 (1945)). Guided by the reasoning in York, the Ninth Circuit held "that the traditional principles governing equitable remedies in federal courts, including the requisite inadequacy of legal remedies, apply when a party requests restitution under the UCL and CLRA in a diversity action." *Id.* at 844. The court went on to find that Sonner's claims for equitable relief were properly dismissed because she failed to allege the lack of an adequate legal remedy. Id.

Apple argues that under *Sonner*, a plaintiff in federal court must allege the lack of an adequate legal remedy in order to state a claim for equitable relief and that Plaintiffs have failed to do so. Plaintiffs argue that (1) Defendant's motion is premature; (2) *Sonner* does not apply to injunctive relief; and (3) even if *Sonner* applies, Plaintiffs adequately alleged that they have no adequate remedy at law in this case.

Plaintiffs argue that Apple's motion is premature for two reasons. Their first reason—that the court should refrain from deciding the motion until after the Ninth Circuit had decided the pending petition for rehearing or rehearing en banc in Sonner-was mooted by the Ninth Circuit's denial of the rehearing petition. See Statement of Recent Decision, Dkt. No. 230. Plaintiffs further assert that the motion is premature because they are not required to make a binding election of remedies at this early stage in the proceedings. Opp. p. 5. But this is not an election of remedies issue. The question is not whether or when Plaintiffs are required to choose between two available inconsistent remedies, it is whether equitable remedies are available to Plaintiffs at all. In other words, the question is whether Plaintiffs have adequately pled their claims for equitable relief, and that question is not premature on a motion to dismiss.

\*3 Plaintiffs next argue that Sonner does not require dismissal of Plaintiffs' claims for injunctive relief because where "state law authorizes the issuance of a permanent injunction, there is no requirement that a plaintiff proceeding in federal court show an inadequate remedy at law to obtain relief." Opp. p. 5. This argument is foreclosed by Sonner. The Sonner court emphasized that the Supreme Court has recognized the "fundamental principle for well over a century that state law cannot expand or limit a federal court's equitable authority," and explained that "a state statute does not change the nature of the federal courts' equitable powers." Sonner, 971 F.3d at 841 (citation omitted). The court expressly found that "even if a state authorizes its courts to provide equitable relief when an adequate legal remedy exists, such relief may be unavailable in federal court because equitable remedies are subject to traditional equitable principles unaffected by state law." Id. (citing York, 326 U.S. at 105-06 & n.3).

Plaintiffs cite to pre-Sonner cases in which federal courts applied state law to determine whether an injunction was warranted. None of those cases involved a state statute that purported to expand the court's equitable powers; rather, in each case the requirements for injunctive relief under state law

were coextensive with the federal common law requirements. See, e.g., Nomadix, Inc. v. Guest-Tek Interactive Entm't, Ltd., No. 2:19-CV-04980-AB-FFM, 2020 WL 1939826, at \*1 (C.D. Cal. Apr. 22, 2020) (granting injunctive relief only after finding, among other things, that "pecuniary compensation would not afford adequate relief"); Brocade Commc'ns Sys., Inc. v. A10 Networks, Inc., No. C 10-3428 PSG, 2013 WL 890126, at \*3 (N.D. Cal. Jan. 23, 2013) ("To prevail on its request for a permanent injunction ... includes a showing that remedies at law are inadequate, and that other equitable considerations warrant entry of an injunction").

Plaintiffs acknowledge that Sonner precludes them from seeking restitution but argue that Sonner should not be extended to preclude claims for injunctive relief. While "[i]njunctive relief [was] not at issue" in Sonner, 971 F.3d at 842, nothing about the Ninth Circuit's reasoning indicates that the decision is limited to claims for restitution. In fact, numerous courts in this circuit have applied Sonner to injunctive relief claims. See e.g., Gibson v. Jaguar Land Rover N. Am., LLC, No. CV2000769CJCGJSX, 2020 WL 5492990, at \*3 (C.D. Cal. Sept. 9, 2020) (dismissing plaintiff's UCL claims for an injunction and restitution because Sonner "very recently made clear" that the requirement to establish an inadequate remedy at law "applies to claims for equitable relief under both the UCL and CLRA."); Teresa Adams v. Cole Haan, LLC, No. SACV20913JVSDFMX, 2020 WL 5648605, at \*2 (C.D. Cal. Sept. 3, 2020) ("The Sonner court derived its rule from broader principles of federal common law ... this broad analysis of the distinction between law and equity [does not] create an exception for injunctions as opposed to other forms of equitable relief. The clear rule in Sonner that plaintiffs must plead the inadequacy of legal remedies before requesting equitable relief therefore applies"); Schertz v. Ford Motor Co., No. CV2003221TJHPVCX, 2020 WL 5919731, at \*2 (C.D. Cal. July 27, 2020) (dismissing claims for an injunction and restitution under the UCL because plaintiff failed to allege the lack of an adequate legal remedy as required under Sonner). This Court agrees with our fellow courts that under Sonner, Plaintiffs are required to allege that they lack an adequate remedy at law in order to seek injunctive relief.

Finally, Plaintiffs argue that they have sufficiently alleged that no adequate legal remedy exists here. They argue that because Apple's repair program is deficient, their alleged injury is "continuing" such that class members with faulty keyboard "seeking to be made whole in the future could only sue Apple repeatedly." Opp. p. 10. Plaintiffs do not explain

why those consumers could not sufficiently be "made whole" by monetary damages. Courts generally hold that monetary damages are an adequate remedy for claims based on an alleged product defect, and reject the argument that injunctive relief requiring repair or replacement is appropriate. *See Philips v. Ford Motor Co.*, No. 14-CV-02989-LHK, 2016 WL 7428810, at \*25 (N.D. Cal. Dec. 22, 2016), *aff'd*, 726 F. App'x 608 (9th Cir. 2018) (the ordinary and more appropriate relief is monetary damages, "not a mandatory injunction requiring Ford to uniformly repair and/or replace" a defect in every vehicle); *see also Victorino v. FCA US LLC*, No. 16CV1617-GPC(JLB), 2018 WL 2455432, at \*20 (S.D. Cal. June 1, 2018) ("monetary damages is the appropriate form of damages" where plaintiffs' claimed injury was the "overpayment of the purchase price of their Class Vehicles").

\*4 Plaintiffs' complaint alleges that class members overpaid for their allegedly defective laptops and incurred various expenses in their attempts to resolve the deficiencies. SAC ¶ 273, 285, 298, 310, 323, 331. Plaintiffs suggest in the Complaint that Apple could have "offer[ed] refunds ... to consumers with failed keyboards." Id. ¶¶ 201, 221. Because Plaintiffs' claims rest on their alleged overpayments and Apple's failure to issue refunds, the Court finds that monetary damages would provide an adequate remedy for the alleged injury. Moreover, the Court finds that the availability of an adequate legal remedy is clear from the face of the SAC and thus further amendment of the complaint would be futile. See Kendall v. Visa U.S.A., Inc., 518 F.3d 1042, 1051 (9th Cir. 2008) (where a plaintiff fails to survive Rule 12(b)(6) scrutiny and "it is clear that the complaint could not be saved by amendment," "[d]ismissal without leave to amend is proper."); Reddy v. Litton Indus., Inc., 912 F.2d 291, 296-97 (9th Cir. 1990) (an "amended complaint may only allege other facts consistent with the challenged pleading").

Thus, Plaintiffs have failed to allege that they lack an adequate remedy at law, as required to state a claim for equitable relief. Plaintiffs' UCL claim is therefore dismissed in its entirety and the remaining claims are dismissed to the extent they seek an injunction, restitution, or other equitable relief.

#### **IV. Conclusion**

For the reasons stated above, Defendant's motion to dismiss is **GRANTED**. Plaintiffs' UCL claim (Claim 1) is **DISMISSED** with prejudice. The remaining claims are **DISMISSED** with prejudice to the extent they seek an injunction, restitution, or other equitable relief.

Case 1:19-md-02875-RMB-SAK Document 1451-1 Filed 08/02/21 Page 175 of 322 PageID: 33237

2020 WL 6047253

IT IS SO ORDERED.

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# Document 1451-1 PageID: 33238

# **Tab 22**

KeyCite Yellow Flag - Negative Treatment
Declined to Follow by Le v. Kohls Department Stores, Inc., E.D.Wis.,
February 8, 2016

2011 WL 5008090 NOT FOR PUBLICATION United States District Court, D. New Jersey.

# In re MAGNESIUM OXIDE ANTITRUST LITIGATION.

Civ. No. 10–5943 (DRD). | Oct. 20, 2011.

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# **OPINION**

DEBEVOISE, Senior District Judge.

\*1 This matter arises out of the consolidation of five separate actions in this Court<sup>1</sup> alleging a conspiracy to fix prices in and allocate shares of the domestic Magnesium Oxide

market from January 2002 to the present ("the Class Period"). On November 15, 2010, Direct Purchaser Plaintiffs ("DP Plaintiffs") Orangeburg Milling Company, Inc., Bar Ale, Inc., and Air Krete, Inc. filed a Class Action Complaint ("CAC") against Defendants Premier Chemicals, LLC ("Premier"), Sumitomo Corporation of America ("Sumitomo"), and YAS, Inc. ("YAS") pursuant to Sections 4 and 16 of the Clayton Act, 15 U.S.C. § 15, 26, alleging violations of Section 1 of the Sherman Act, 15 U.S.C. § 1, and seeking class certification under Federal Rule of Civil Procedure 23(b)(2) and (3), declaratory judgment, treble damages, costs and attorneys' fees, and an injunction. On December 30, 2010, DP Plaintiffs filed an Amended CAC to add additional factual allegations in support of their claims.

1 See Docket Nos. 10-cv-5174, 10-cv-5352, 10-cv-6095, and 10-cv-6093, and 10-cv-5943, all of which were consolidated under Docket No. 10-cv-5943.

On October 7, 2010, Indirect Purchaser Plaintiffs ("IP Plaintiffs") Ronald Hayek, Daniel, Walker, Sue Walker, and John Bidart filed a CAC against Defendants under Section 16 of the Clayton Act, alleging violations of Section 1 of the Sherman Act, and under various state antitrust and consumer protection laws. IP Plaintiffs seek similar relief as DP Plaintiffs. On December 31, 2010, IP Plaintiffs filed an Amended CAC to add similar factual allegations as those added by DP Plaintiffs in their Amended CAC.

To be sure, IP Plaintiffs seek only injunctive relief for Defendants' alleged violations of federal antitrust laws, as only direct purchasers may bring federal antitrust actions for damages. *Illinois Brick v. Illinois*, 431 U.S. 720, 97 S.Ct. 2061, 52 L.Ed.2d 707 (1977).

On March 1, 2011, Defendants filed a Motion to Dismiss<sup>3</sup> all of Plaintiffs' claims pursuant to Federal Rule of Civil Procedure 12(b)(6). For the reasons set forth below, Defendants' motion is granted. No Defendant is entitled to dismissal of Plaintiffs' federal and state antitrust claims on the merits because Plaintiffs sufficiently allege a meeting of the minds among all Defendants to fix prices in and allocate shares of the domestic Magnesium Oxide market. However, Defendants are entitled to dismissal of IP Plaintiffs' federal and state antitrust claims and the majority of their consumer protection claims for lack of standing. In addition, those consumer protection claims under which IP Plaintiffs have standing are dismissed to the extent they are based on allegations of fraud because those allegations do not comply with the requirements of Federal Rule of Civil Procedure

9(b). Finally, Plaintiffs' federal and state antitrust claims are dismissed because they are time-barred by their respective statutes of limitations.

In fact, Sumitomo, Premier, and YAS each filed separate motions to dismiss. However, each joined in the others' arguments. Therefore, for the sake of simplicity and brevity, the Court will treat them as a single motion.

### I. BACKGROUND

Magnesium Oxide ("MgO") is a solid, white, naturally occurring mineral that is used in producing a wide variety of products, including refractory products, animal feeds, fertilizers, electrical insulation, and pharmaceuticals. It is formed by an ionic bond between one magnesium atom and one oxygen atom. MgO can be mined from magnesite or processed from seawater or subterranean brines containing magnesium chloride. This case concerns the two most common forms of MgO: Caustic-calcined magnesia ("CCM") and dead-burned magnesia ("DBM"). DBM and CCM are produced differently and have different commercial applications.<sup>4</sup>

CCM "is manufactured at lower temperatures than [DBM] and is used in products like animal feeds and fertilizers." (Direct CAC ¶ 25; Indirect CAC ¶ 31.) DBM, on the other hand, "is most often used in refractory applications." (*Id.*)

\*2 In 2000, according to the CACs, domestic consumption of DBM and CCM came from two sources: the United States and China. Roughly 50% of CCM "and a lesser amount of" DBM consumed in the United States were produced domestically, while the rest was imported from China. (Direct Purchasers' Consolidated Amended Class Action Complaint ("Direct CAC") ¶ 27; (Indirect Purchasers' Consolidated Amended Class Action Complaint ("Indirect CAC") ¶ 33.) At that time, Premier allegedly maintained control over the majority of DBM and CCM consumed in the United States by (1) purchasing imported CCM and DBM for resale to its customers in the United States, and (2) sourcing magnesite from China for production into DBM to be sold domestically.

"Sumitomo similarly purchased Chinese MgO but only [DBM] for resale to its U.S. customers" and "sourced magnesite from China for manufacture into [DBM] for sale in the U.S." (Direct CAC ¶ 27; Indirect CAC ¶ 34.) To do so, it enlisted the help of YAS to (1) "facilitate[ ][its] purchases of

Chinese magnesite" (Direct CAC ¶ 27; Indirect CAC ¶ 35), and (2) purchase Chinese DBM for resale in the United States.

This arrangement proved successful because Hideo Sumikawa, the current president of YAS, previously worked for Sumitomo and has since maintained relationships with certain Chinese magnesite mines. "In particular, Sumitomo, through Coy Akiyama—head of Sumitomo's inorganic chemicals unit—purchases [DBM] from Chinese mines that Sumikawa (YAS) has facilitated, thereby allowing Sumitomo and YAS to participate together in the U.S. MgO market." (Direct CAC ¶ 33; Indirect CAC ¶ 41.)

According to Plaintiffs, sometime before the Class Period, Premier "saw its share of MgO markets shrink due to increased Chinese competition." (Direct CAC ¶ 28; Indirect CAC ¶ 36.) Specifically, "cheaper imports, mainly from China ha [d] replaced some of the U.S. domestic production, notably affecting Premier." (Direct CAC ¶ 29; Indirect CAC ¶ 37.) Thus, during the Class Period, Premier and Sumitomo allegedly bought nearly all of the Chinese DBM available for purchase and resold it to their customers in the United States.

In addition, Plaintiffs allege that, "[d]uring the Class Period, with some limited exceptions, the MgO markets were considered to be fairly saturated, with limited potential for growth." (Direct CAC ¶ 30; Indirect CAC ¶ 38.) However, "[i]nstead of competing, representatives from Premier, Sumitomo, and YAS began meeting regularly to discuss fixing U.S. MgO prices and allocating MgO markets." (Direct CAC ¶ 31; Indirect CAC ¶ 39.) Specifically, Plaintiffs allege a conspiracy among Premier, Sumitomo, and YAS to (1) fix prices in and allocate shares of the domestic DBM market and (2) allocate the domestic CCM market to Premier so that it could fix prices in that market, which resulted in Plaintiffs' purchasing DBM and CCM at artificially high prices.

# i. The DBM and CCM Agreements

\*3 Plaintiffs allege that, during the Class Period, Cary W. Ahl, Sr. Premier's then-president, "regularly called" Mr. Sumikawa of YAS "to discuss fixing Premier's and Sumitomo's [DBM] prices and allocating their respective MgO accounts in the U.S." (Direct CAC ¶ 34; Indirect CAC ¶ 42.) These market allocation and price-fixing schemes were allegedly implemented by Mr. Ahl and his successors at Premier and Terry Wakisama at Sumitomo.

In the summer of 2004, Coy Akiyama of Sumitomo, Mr. Sumikawa of YAS, Gary Vannorsdel, an animal nutrition broker, and Mr. Vannorsdel's son, met at a Holiday Inn, in Tulsa, Oklahoma, to discuss plans for Sumitomo to enter the CCM market without upsetting Premier. Sumitomo had been shipping DBM to the United States on "partially empty barges and wanted to maximize efficiencies by filling these barges with [CCM] for sale to the western U.S." (Direct CAC ¶ 39; Indirect CAC ¶ 48.) Indeed, DBM shipments filled only half of Sumitomo's New Orleans barge capacity. Apparently, "Tulsa was the only port that could accommodate this barge, and Sumitomo had access to a very large storage facility in Tulsa." (Direct CAC ¶ 36; Indirect CAC ¶ 44.)

At the Tulsa meeting, "[i]n the course of discussing a strategy for Sumitomo to enter the U.S. [CCM] market, Akiyama (Sumitomo) recounted to Sumikawa (YAS) multiple discussions between him and Ahl where Ahl had called Akiyama to set [DBM] prices; to allocate [DBM] markets; and to ensure that Sumitomo was maintaining its agreement with Premier to fix [DBM] prices and allocate [DBM] markets." (Direct CAC ¶ 40; Indirect CAC ¶ 49.) At one point, Mr. Vannorsdel "expressed concern about compromising his relationship with Premier by helping facilitate Sumitomo and YAS's involvement" in the CCM market, to which Mr. Akiyama responded, "'Don't be concerned because we [Sumitomo] talk with Premier on a daily basis to set prices and to discuss what accounts they can have.' "(Direct CAC ¶ 41; Indirect CAC ¶ 50.)

Shortly after the Tulsa meeting, Mr. Ahl discovered Sumitomo's plan to enter the CCM market and retaliated by dropping DBM prices. As a result, Sumitomo did not follow through with its plans to enter the CCM market. Following the [CCM]-related message that Premier sent to Sumitomo and YAS via Premier's pre-market-entry retaliation, Sumitomo and YAS illegally agreed with Premier to remain out of the [CCM] market—a market Sumitomo, as a rational profit-seeking entity, was motivated to enter—thus allowing Premier to maintain its control over [CCM] pricing." (Direct CAC ¶ 43; Indirect CAC ¶ 52.)

5 These prices were later restored.

## ii. Fraudulent Concealment

Plaintiffs allege that the MgO conspiracy was "inherently self-concealing" and that Defendants took affirmative measures to conceal it. (Direct CAC  $\P$  48–49; Indirect CAC  $\P$  55–56.) Specifically, Plaintiffs allege that "[D]efendants

met secretly and among themselves for the express purpose of fixing prices and allocating markets of domestically sold MgO." (Direct CAC ¶ 50; Indirect CAC ¶ 57.) In addition, Defendants allegedly explained increases in the price of MgO "by references to tight supply, thinning margins, and increased energy and freight costs." (Direct CAC ¶ 51; Indirect CAC ¶ 58.) As a result, Plaintiffs allege that "neither [P]laintiffs nor the class members had knowledge of any of the foregoing violations, and neither [P]laintiffs nor the class members, until recently, could have discovered through reasonable diligence that [D]efendants and their coconspirators had engaged in the foregoing violations." (Direct CAC ¶ 49; Indirect CAC ¶ 56.)

# iii. The Complaints

\*4 On November 15, 2010, DP Plaintiffs—i.e. those who purchased either DBM or CCM directly from one or more Defendants, their predecessors, subsidiaries, or coconspirators during the Class Period—filed a CAC against Defendants under Sections 4 and 16 of the Clayton Act alleging violations of Section 1 of the Sherman Act, and seeking class certification under Federal Rule of Civil Procedure 23(b)(2) and (3), declaratory judgment, treble damages, costs and attorneys' fees, and an injunction. On December 30, 2010, DP Plaintiffs filed an Amended CAC to add additional factual allegations in support of their claims.

On October 7, 2010, IP Plaintiffs—i.e. those who purchased products containing DBM or CCM that was manufactured, distributed or sold by one or more Defendants, their predecessors, subsidiaries, or co-conspirators during the Class Period—filed a CAC against Defendants under Section 16 of the Clayton Act, alleging violations of Section 1 of the Sherman Act, and under various state antitrust and consumer protection laws, and seeking similar relief as the DP Plaintiffs. On December 31, 2010, IP Plaintiffs filed an Amended CAC to add similar factual allegations as those added by DP Plaintiffs in their Amended CAC.

# II. DISCUSSION

Defendants now move to dismiss both Amended CACs pursuant to Federal Rule of Civil Procedure 12(b)(6). In doing so, Defendants argue that Plaintiffs (1) lack standing to assert their federal and state antitrust claims; (2) fail to allege a plausible antitrust conspiracy to fix DBM prices, allocate portions of the domestic DBM market, and allocate

the domestic CCM market to Premier; and (3) fail to plead fraudulent concealment with particularity to equitably toll the applicable federal and state antitrust statutes of limitations. Defendants further argue that IP Plaintiffs' lack standing to assert their consumer protection and unfair competition claims, and that those claims are improperly pled.

## A. Standard of Review

In assessing the parties' arguments, the Court must apply the standard of review applicable to requests for dismissal pursuant to Federal Rule of Civil Procedure 12(b)(6). That rule permits a court to dismiss a complaint for failure to state a claim upon which relief can be granted. When considering a Rule 12(b)(6) motion, the Court must accept the factual allegations in the complaint as true and draw all reasonable inferences in favor of the plaintiff. *Morse v. Lower Merion Sch. Dist.*, 132 F.3d 902, 906 (3d Cir.1997). The Court's inquiry, however, "is not whether plaintiffs will ultimately prevail in a trial on the merits, but whether they should be afforded an opportunity to offer evidence in support of their claims." *In re Rockefeller Ctr. Prop., Inc.*, 311 F.3d 198, 215 (3d Cir.2002).

The Supreme Court recently clarified the Rule 12(b)(6) standard in two cases: Ashcroft v. Iqbal, 556 U.S. 662, 129 S.Ct. 1937, 173 L.Ed.2d 868 (2009), and Bell Atlantic Corporation v. Twombly, 550 U.S. 544, 127 S.Ct. 1955, 167 L.Ed.2d 929 (2007). The decisions in those cases abrogated the rule established in Conley v. Gibson, 355 U.S. 41, 45-46, 78 S.Ct. 99, 2 L.Ed.2d 80 (1957), that "a complaint should not be dismissed for failure to state a claim unless it appears beyond doubt that the plaintiff can prove no set of facts in support of his claim, which would entitle him to relief." In contrast, Bell Atlantic, 550 U.S. at 545, held that "[f]actual allegations must be enough to raise a right to relief above the speculative level." Thus, the assertions in the complaint must be enough to "state a claim to relief that is plausible on its face," id. at 570, meaning that the facts alleged "allow [ ] the court to draw the reasonable inference that the defendant is liable for the conduct alleged." *Iqbal*, 129 S.Ct. at 1949; see also, Phillips v. County of Allegheny, 515 F.3d 224, 234–35 (3d Cir.2008) (In order to survive a motion to dismiss, the factual allegations in a complaint must "raise a reasonable expectation that discovery will reveal evidence of the necessary element," thereby justifying the advancement of "the case beyond the pleadings to the next stage of litigation.").

\*5 When assessing the sufficiency of a complaint, the Court must distinguish factual contentions—which allege behavior on the part of the defendant that, if true, would satisfy one or more elements of the claim asserted—from "[t]hreadbare recitals of the elements of a cause of action, supported by mere conclusory statements." *Iqbal*, 129 S.Ct. at 1949. Although for the purposes of a motion to dismiss the Court must assume the veracity of the facts asserted in the complaint, it is "not bound to accept as true a legal conclusion couched as a factual allegation." *Id.* at 1950. Thus, "a court considering a motion to dismiss can choose to begin by identifying pleadings that, because they are no more than conclusions, are not entitled to the assumption of truth." *Id.* 

When a claim is dismissed pursuant to Federal Rule of Civil Procedure 12(b)(6), leave to amend and reassert that claim is ordinarily granted. *In re Burlington Coat Factory Litig.*, 114 F.3d 1410, 1434 (3d Cir.1997). A claim may be dismissed with prejudice, however, if amending the complaint would be futile. *Id*. "Futile," as used in this context, means that the complaint could not be amended to state a legally-cognizable claim. *Id*. (citing *Glassman v. Computervision Corp.*, 90 F.3d 617, 623 (1st Cir.1996)).

# **B. Plaintiffs' Standing to Bring Antitrust Claims**

Standing is a jurisdictional prerequisite under Article III of the United States Constitution. "Under Article III, the Federal Judiciary is vested with the 'Power' to resolve not questions and issues but 'Cases' or 'Controversies.' "Arizona Christian Sch. Tuition Org. v. Winn, —U.S. —, , —, 131 S.Ct. 1436, 1441, 179 L.Ed.2d 523 (2011). "To state a case or controversy under Article III, a plaintiff must establish standing." *Id.* at 1442 (citing Allen v. Wright, 468 U.S. 737, 751, 104 S.Ct. 3315, 82 L.Ed.2d 556 (1984)). The Supreme Court explained the elements of standing in Lujan v. Defenders of Wildlife, 504 U.S. 555, 560–61, 112 S.Ct. 2130, 119 L.Ed.2d 351 (1992):

"First, the plaintiff must have suffered an 'injury in fact'—an invasion of a legally protected interest which is (a) concrete and particularized, and (b) 'actual or imminent, not "conjectural" or "hypothetical." 'Second, there must be a causal connection between the injury and the conduct complained of—the injury has to be 'fairly ... trace[able] to the challenged action of the defendant, and not ... th[e] result [of] the independent action of some third party not before the court .' Third, it must be 'likely,' as opposed to merely 'speculative,' that the injury will be 'redressed by a favorable decision.' "

Defendants argue that Plaintiffs lack antitrust standing because they do not identify whether they purchased DBM or CCM. Specifically, Defendants contend that the alleged agreements regarding DBM and CCM, respectively, amount to "two conspiracies [that] are allegedly directed at different purchasers and encompass different time frames[,] and [n]othing indicates that anticompetitive activity in one market would have an effect on prices in the other market." (YAS Br., 9.) "Under these circumstances," according to Defendants, "a purchaser of [DBM] would suffer no redressable injury from anticompetitive conduct in the [CCM] market, and would accordingly lack standing to maintain claims based on such conduct (and vice versa)." (*Id.*).

\*6 This argument is unavailing because, as discussed fully below, Plaintiffs allege a single conspiracy in the domestic MgO market comprised of two agreements: one to fix prices in and allocate shares of the domestic DBM market, and one to allocate the domestic CCM market to Premier. These agreements are interdependent in that Defendants entered into the CCM agreement in order to maintain the DBM agreement. As a result, price-fixing in the DBM market has an effect on prices in the CCM market, and vice versa, because the absence of one agreement would eliminate the consideration for the other.

As a general matter, DP Plaintiffs' allegation that they were "injured by having paid more for MgO6 than they otherwise would have paid absent [D]efendants' unlawful conduct" (Direct CAC ¶ 56) is sufficient to establish antitrust standing. Standing to sue under Section 4 of the Clayton Act is determined by a five-factor test: 7 "(1) the causal connection between the antitrust violation and the harm to the plaintiff; (2) whether the plaintiff's alleged injury is of the type that the antitrust laws were intended to redress; i.e., did the plaintiff suffer antitrust injuries; (3) the directness of the injury; (4) the existence of more direct victims of the violation; and (5) the potential for duplicative recovery or complex apportionment of damages." In re Warfarin Sodium Antitrust Litig., 214 F.3d 395, 399 (3d Cir.2000) (citing Associated General Contractors of California, Inc. v. California State Council of Carpenters, 495 U.S. 519, 538 (1983). Here, there is little doubt that those who purchased DBM and/or CCM directly from Defendants at supracompetitive prices have standing to sue for damages under Section 4 and for injunctive relief under Section 16. See id. at 401 ("It is difficult to imagine a more formidable demonstration of antitrust injury" than supra-competitive pricing.); In re Mercedez Benz Anti*Trust Litig.*, 157 F.Supp.2d 355, 364 (D.N.J.2001) ("Where, as here, it is alleged that consumers paid a price higher than the price that would have been offered had the dealers been competing, the purpose of the antitrust laws is obviously thwarted."). Thus, DP Plaintiffs have standing to pursue their antitrust claims.

- MgO collectively refers to DBM and/or CCM. (Direct CAC ¶ 1.)
- As discussed further below, standing to assert claims for injunctive relief under Section 16 of the Clayton Act are analyzed under a more relaxed standard. *See In re Warfarin*, 214 F.3d at 399.

IP Plaintiffs, however, do not. While they seek solely injunctive relief under Section 16 of the Clayton Act—and therefore are not subject to the aforementioned five-factor test, see Note 7—they must still allege "(1) [a] threatened loss or injury cognizable in equity; (2) proximately resulting from the alleged antitrust injury." In re Warfin, 214 F.3d at 400. In analyzing whether an antitrust injury proximately caused an alleged loss to an indirect purchaser, this Circuit has been guided by the Supreme Court's decision in Shield of Virginia v. McCready, 457 U.S. 465, 102 S.Ct. 2540, 73 L.Ed.2d 149 (1982). McCready explained that "an antitrust violation may be expected to cause ripples of harm to flow through the Nation's economy; but ... [i]t is reasonable to assume that Congress did not intend to allow every person tangentially affected by an antitrust violation to maintain an action." 457 U.S. at 476. Thus, in determining whether an injury was proximately caused by an antitrust violation for Article III standing purposes, courts should "look (1) to the physical and economic nexus between the alleged violation and the harm to the plaintiff, and (2) more particularly, to the relationship of the injury alleged with those forms of injury about which Congress was likely to have been concerned in making defendant's conduct unlawful and in providing a private remedy." Id. at 478. In doing so, they should consider whether the plaintiff's injury is "inextricably intertwined with the injury that the conspirators sought to inflict," In re Warfarin, 214 F.3d at 400-01 (purchasers of prescription drug whose active ingredient was the subject of a price-fixing conspiracy maintained standing to sue as indirect purchasers because "the excess amount paid" for the drug was "inextricably intertwined with the injury [Defendant] aimed to inflict"), or, put another way, "whether the injury alleged is so integral an aspect of the conspiracy alleged, there can be no question but that the loss was precisely the type of loss that the claimed violations ... would be likely to

cause." *McCready*, 457 U.S. at 479 (quotations and citations omitted) (alleged conspiracy among psychiatrists and Blue Shield to take patients away from psychologists by refusing to reimburse Blue Shield subscribers for psychotherapeutic services resulted in "clearly foreseeable" harm to Blue Shield subscribers and "was a necessary step in effecting the ends of the alleged illegal conspiracy.").

Although that decision analyzed proximate causation in the context of a Section 4 claim for damages, the Court of Appeals has applied its analysis to Section 16 claims because proximate cause is an element of standing under both. See In re Warfin Sodium Antitrust Litig., 214 F.3d 395, 400–01 (3d Cir.2000).

\*7 Here, IP Plaintiffs allege that "as a direct and proximate result of Defendants' and their co-conspirators' unlawful contract, combination and conspiracy, Plaintiffs and the Class members were injured and financially damaged in their business and property by having paid more for MgO Products than they would have absent Defendants' and their coconspirators' unlawful conduct." (Indirect CAC ¶ 54.) However, they fail to specify which MgO products—i.e. products containing DBM or CCM—they purchased. The mere fact that a product contains DBM or CCM does not necessarily mean that an increase in the price of that product is "inextricably intertwined" with, or an "a necessary step in achieving the ends" of, the alleged conspiracy to fix prices in and allocate shares of the domestic DBM and CCM markets. Indeed, the price of DBM and CCM would have a minimal foreseeable effect on the price of products containing trace amounts of them, but a significant foreseeable effect on the price of products in which they are major ingredients. Thus, without knowing which specific products IP Plaintiffs purchased, it is impossible to determine whether an increase in their price is the type of injury that furthers the object of the alleged conspiracy to fix prices in and allocate shares of the domestic DBM and CCM markets. Accordingly, IP Plaintiffs' federal antitrust claims are dismissed for lack of standing.<sup>9</sup> However, IP Plaintiffs are granted leave to amend in order to allege (1) the specific purchased products containing DBM or CCM and (2) the nexus between an increase in the price of those products and the alleged conspiracy to fix prices in and allocate shares of the domestic DBM and CCM markets.

IP Plaintiffs also lack standing to assert their state antitrust claims because those claims are construed in accordance with federal antitrust principles. *See In re Digital Music Antitrust Litig.*, 592 F.Supp.2d 435, 448 n. 21 (S.D.N.Y.2008) (Arizona, California, District of

Columbia, Iowa, Kansas, Maine, Michigan, Minnesota, North Carolina, South Dakota, Vermont, West Virginia, Wisconsin), rev'd on other grounds by, Starr v. Sony BMG Music Entm't., 592 F.3d 314 (2d Cir.2010); T.W. Elec. Serv., Inc. v. Pacific Elec. Contractors Ass'n, 809 F.2d 626, 635-36 (9th Cir.1987) (Hawaii); Gutnayer v. Cendant Corp., 116 Fed. App'x 758, 761 (7th Cir.2004) (Illinois); Monsanto Co. v. Swann, No. 4:00-CV-1481, 2001 WL 34079480, at \*3 (E.D.Mo. Sept.19, 2001) (Mississippi); Neb.Rev.Stat. § 59–829 (2010) (Nebraska); Nev.Rev.Stat. § 598A.050 (2011) (Nevada); Minuteman, LLC v. Microsoft Corp. ., 147 N.H. 634, 637, 795 A.2d 833 (N.H.2002) (New Hampshire); Clough v. Rush, 959 F.2d 182, 187 (10th Cir.1982) (New Mexico); Fido's Fences v. Canine Fence Co., 672 F.Supp.2d 303, 313 (E.D.N.Y.2009) (New York); Westgo Indus., Inc. v. W.J. King Co., Civil No. A3-75-82, 1981 WL 2064, at \*6 (D.N.D. Mar.1, 1981) (North Dakota); Oregon Laborers-Employees Health & Welfare Trust Fund v. Phili Morris, Inc., 185 F.3d 957, 963 n. 4 (9th Cir.1999) (Oregon); In re Refalen Antitrust Litig., 221 F.R.D. 260, 278-79 (D.Mass.2004) (Tennessee); Am. Airlines v. Christensen, 967 F.2d 410, 414 (10th Cir.1992) (Utah).

Defendants further argue that IP Plaintiffs lack standing to assert their state law antitrust claims, with the exception of Iowa and California, because they only allege purchasing MgO products in Iowa and California. Specifically, Defendants contend that IP Plaintiffs "have no standing to bring claims based on violations of states in which they neither reside nor purchased any MgO products." (Sumitomo Br. (IP Pl.), 4.) IP Plaintiffs counter that "Defendants improperly confuse 'standing' with class certification issues," which, at this point, are premature. (IP Pl's Br., 30.) Specifically, IP Plaintiffs maintain that they "are not bringing claims in their own name in other states; rather they are seeking to represent similarly situated persons in other states," and that "[t]his issue, improperly raised by Defendants on a motion to dismiss will be addressed at class certification under Rule 23." (*Id.* at 31) (emphasis in original).

It is well-settled that a named plaintiff in a class action lawsuit is required to establish Article III standing. *See Lewis v. Casey, 518 U.S. 343, 357, 116 S.Ct. 2174, 135 L.Ed.2d 606 (1996)* ("That a suit may be a class action ... adds nothing to the question of standing, for even named plaintiffs who represent a class must allege and show that they personally have been injured, not that injury has been suffered by other, unidentified members of the class to which they belong and which they purport to represent." (quotations and citations omitted)); *Warth v. Seldin, 422 U.S. 490, 501, 95 S.Ct. 2197, 45 L.Ed.2d 343 (1975)* ("[T]he plaintiff still must allege a

distinct and palpable injury to himself, even if it is an injury shared by a large class of other possible litigants."); *O'Shea v. Littleton*, 414 U.S. 488, 494, 94 S.Ct. 669, 38 L.Ed.2d 674 (1974) ("[I]f none of the named plaintiffs purporting to represent a class establishes the requisite of a case or controversy with the defendants, none may seek relief on behalf of himself or any other member of the class." (citations omitted)); *Winer Family Trust v. Queen*, 503 F.3d, 319, 326 (3d Cir.2007) ("The initial inquiry in either case is whether the lead plaintiff individually has standing.").

\*8 Less well-settled is whether, pre-class certification, named plaintiffs are required to establish standing for each and every claim set forth in a class action complaint, or whether it is sufficient to establish standing for a single claim because a court will determine if the named plaintiffs have standing to represent the unnamed class members seeking redress under the balance of asserted claims during the class certification process pursuant to Federal Rule of Civil Procedure 23. This issue typically arises in cases, such as this one, where named plaintiffs assert analogous causes of action under the laws of many states but cannot specifically tie their injuries to each state. Indeed, here, IP Plaintiffs, who allege that they purchased MgO products in Iowa and California, assert violations of twenty-five states' antitrust laws. <sup>10</sup>

10 At this time, IP Plaintiffs lack Article III standing to assert violations of the following state antitrust laws because they fail to allege a causal connection between their injuries and the conduct prohibited by the laws of those states, which require a showing that such conduct occurred, or whose effect was felt, in-state. See A.R.S. § 44–1402 (Arizona) ("A contract, combination or conspiracy between two or more persons in restraint of, or to monopolize, trade or commerce, any part of which is within this state, is unlawful"); DC ST § 28-4502 (District of Columbia) (same); HRS § 480-4 (Hawaii) (same); 10 M.R.S.A. § 1101 (Maine) (same); SDCL § 37-1-3.1 (South Dakota) (same); K.S.A. § 50–101 (Kansas) ("A trust is a combination of capital, skill, or acts, by two or more persons," among other things, "[t]o fix any standard or figure, whereby such person's price to the public shall be, in any manner, controlled or established, any article or commodity of merchandise, produce or commerce intended for sale, use or consumption in this state"); M.C.L.A. §§ 445.771, 445.772 (Michigan) ("A contract, combination, or conspiracy between 2 or more persons in restraint of, or to monopolize, trade or commerce in a relevant market is unlawful.... Relevant market means the geographical area of actual or potential competition in a line of trade or commerce, all or any part of which is within this state"); M.S.A. § 325D.54 (Minnesota) (act applies to "(a) any contract, combination, or conspiracy when any part thereof was created, formed, or entered into in this state; and (b) any contract, combination, or conspiracy, wherever created, formed, or entered into; any establishment, maintenance, or use of monopoly power; and any attempt to establish, maintain, or use monopoly power; whenever any of the foregoing affects the trade or commerce of this state."); Neb. Rev. St. § 59–801 (Nebraska) ("Every contract, combination in the form of trust or otherwise, or conspiracy in restraint of trade or commerce, within this state, is hereby declared to be illegal."); N.R.S. § 598A.060 (Nevada) (same); N.M.S .A. § 1978, 57–1–1 (New Mexico) (same); W.Va.Code § 47–18–3 (West Virginia) (same); NY GBL § 340 (New York) (Every contract, agreement, arrangement or combination whereby ... [c]ompetition or the free exercise of any activity in the conduct of any business, trade or commerce or in the furnishing of any service in this state is or may be restrained ... is hereby declared to be against public policy, illegal and void."); N.C.G.S.A. § 75-1 (North Carolina) ("Every contract, combination in the form of trust or otherwise, or conspiracy in restraint of trade or commerce in the State of North Carolina is hereby declared to be illegal."; NDCC, 51-08.1-01, 02 (North Dakota) ("A contract, combination, or conspiracy between two or more persons in restraint of, or to monopolize, trade or commerce in a relevant market is unlawful.... Relevant market means the geographical area of actual or potential competition in a line of commerce, all or any part of which is within this state."); O.R.S. 646.705 (Oregon) ("As used in ORS 136.617 and 646.705 to 646.805, 'trade or commerce' means trade or commerce within the state; or between the state and any state, territory, or foreign nation."); (Tennessee) T .C.A. § 47-25-101 ("All arrangements, contracts, agreements, trusts, or combinations between persons or corporations made with a view to lessen, or which tend to lessen, full and free competition in the importation or sale of articles imported into this state, or in the manufacture or sale of articles of domestic growth or of domestic raw material, and all arrangements, contracts, agreements, trusts, or combinations between persons or corporations designed, or which tend, to advance, reduce, or control the price or the cost to the producer or the consumer of any such product or article, are declared to be against public policy, unlawful, and void."). IP Plaintiffs' allegations that "[P]rices for MgO and MgO Products were raised, fixed, maintained, and stabilized at artificially high levels throughout the states," and "Defendants' illegal conduct

had a substantial effect on commerce in the above states" (Indirect CAC ¶¶ 72, 73) are conclusory and fail to specifically tie their injuries to the alleged MgO conspiracy occurring or its effects in those states.

IP Plaintiffs lack statutory standing to sue under Utah's antitrust laws because they have a citizenship/residency requirement. See U.C.A. §§ 1953 76–10–919 ("A person who is a citizen of this state or a resident of this state and who is injured or is threatened with injury in his business or property by a violation of the Utah Antitrust Act may bring an action for injunctive relief and damages, regardless of whether the person dealt directly or indirectly with the defendant."), and under Illinois's antitrust laws because they do not allow a private right of action. See 740 ILCS 10/7 ("This State, counties, municipalities, townships and any political subdivision organized under the authority of this State, and the United States, are considered a person having standing to bring an action under this subsection.").

However, IP Plaintiffs apparently have standing to sue under Mississippi, New Hampshire, Vermont, and Wisconsin antitrust laws, as they provide a private right of action and have no discernible requirement of in-state conduct or effect, or residency. *See* Miss.Code Ann. §§ 75–21–1, 9 (Mississippi); N.H. Rev. Stat § 356:1 (New Hampshire); 9 V.S.A. §§ 2453, 2465 (Vermont); W.S.A. §§ 133.03, 133.18 (Wisconsin).

Courts, including this one, have held that "the fact that the named Plaintiffs may not have individual standing to allege violations of ... laws in states other than those in which they purchased Defendants' [product] is immaterial [because] [t]he issue ... is one of predominance—whether questions of law or fact common to all class members predominate over any questions affecting only individual members." Ramirez v. STI Prepaid LLC, 644 F.Supp.2d 496, 505 (D.N.J.2009) (quotations and citations omitted); see also In re Grand Theft Auto Video Game Consumer Litig. (No. II). No. 06-MD-1739, 2006 WL 3039993, at \*3 (S.D.N.Y. Oct. 25, 2006) ("The relevant question ... is not whether the Named Plaintiffs have standing to sue Defendants—they most certainly do—but whether their injuries are sufficiently similar to those of the purported Class to justify the prosecution of a nationwide class action. This question is, at least in the first instance, appropriately answered through the class certification process."); In re Buspirone Patent Litig., 185 F.Supp.2d 363, 377 (S.D.N.Y.2002) ("[T]hese alleged problems with standing will not arise unless class certification is granted. If certification is granted, the proposed class would contain plaintiffs who have personal standing to raise claims under the laws governing purchases in all of the [] states, and the only relevant question about the named plaintiffs' standing to represent them will be whether the named plaintiffs meet the ordinary criteria for class standing ...").

Other courts find that they must initially "review[] the standing of actual, not proposed plaintiffs" to assert the claims in a class action complaint because "[t]he alternative ... would allow named plaintiffs in a proposed class action, with no injuries in relation to the laws of certain states referenced in their complaint, to embark on lengthy class discovery with respect to injuries in potentially every state in the Union." In re Wellbutrin XL Antitrust Litig., 260 F.R.D. 143, 154-56 (E.D.Pa.2009); see also In re Potash Antitrust Litig., 667 F.Supp.2d 907, 924 (N.D.III.2009) (named plaintiffs are required to establish standing for each claim under which they purport to represent class members because "[t]o have standing as a class representative, the plaintiff must be part of the class, that is, he must possess the same interest and suffer the same injury shared by all members of the class he represents." (quotations and citations omitted)), rev'd on other grounds by, Minn-Chem Inco. v. Agrium Inco., — F.3d—, No. 10-1712, 2011 WL 4424789 (7th Cir. Sept.23, 2011); In re Packaged Ice Antitrust Litig., 08-md-01952, 2011 WL 891160, at \*11 (E.D.Mich. Mar. 11, 2011) ("[N]amed plaintiffs lack standing to assert claims under the laws of the states in which they do not reside or in which they suffered no injury.").

\*9 Two Supreme Court decisions, Amchem Prods. Inc. v. Windsor, 521 U.S. 591, 117 S.Ct. 2231, 138 L.Ed.2d 689 (1997) and Ortiz v. Fibreboard Corp., 527 U.S. 815, 119 S.Ct. 2295, 144 L.Ed.2d 715 (1999), are at the heart of this issue. In Amchem, the Supreme Court reviewed a challenge to certification of a global settlement class involving persons who were exposed to asbestos. See 521 U.S. at 591-92. In doing so, it analyzed the role of settlement in determining class certification under Rule 23, as well as arguments set forth by objectors that certain members of the settlement class lacked standing to sue because they had not sustained a cognizable injury or because their injury was not redressable. *Id.* at 612. The Court declined to reach the standing arguments because it found the class certification issues under Rule 23 to be dispositive. *Id.* Consequently, the Court held that because resolution of the class certification issues "here is logically antecedent to the existence of Article III issues, it is appropriate to reach them first." Id. (citation omitted).

The Court further explained that it was "follow[ing] the path taken by the [Third Circuit] Court of Appeals" in "declin[ing] to reach these issues because they 'would not

exist but for the [class-action] certification." "Id. (quoting Georgine v. Amchem Prods., Inc., 83 F.3d 610, 623 (3d Cir.1996)). To be sure, in Georgine, the Court of Appeals, when faced with class certification and Article III issues simultaneously, decided the class certification issues first because they were dispositive. 83 F.3d at 623. In doing so, the Court found "it prudent not to decide issues unnecessary to the disposition of the case, especially when many of these issues implicate constitutional questions." Id. (citing Spector Motor Serv., Inc. v. McLaughlin, 323 U.S. 101, 105, 65 S.Ct. 152, 89 L.Ed. 101 (1944) (expressing the rule that courts will avoid constitutional questions when possible)). Thus, these rulings echo the "fundamental and longstanding principle of judicial restraint [] requir[ing] that courts avoid reaching constitutional questions in advance of the necessity of deciding them." Lyng v. Northwest Indian Cemetery Protective Ass'n, 485 U.S. 439, 445, 108 S.Ct. 1319, 99 L.Ed.2d 534 (1988).

The *Ortiz* court also dealt with certification issues regarding a global settlement class for asbestos related injuries and arguments regarding the Article III standing of certain class members who petitioners alleged did not suffer an injury-infact. 527 U.S. at 821, 831. As in *Amchem*, the Court decided to address the class certification issues before the Article III questions. *Id.* at 831. In doing so, it explained:

Ordinarily, of course, this or any other Article III court must be sure of its own jurisdiction before getting to the merits. *Steel Co. v. Citizens for a Better Environment,* 523 U.S. 83, 88–89, 118 S.Ct. 1003, 140 L.Ed.2d 210 (1998). But the class certification issues are, as they were in *Amchem,* "logically antecedent" to Article III concerns, 521 U.S., at 612, 117 S.Ct. 2231, 138 L.Ed.2d 689, and themselves pertain to statutory standing, which may properly be treated before Article III standing, *see Steel Co., supra,* at 92, 523 U.S. 83, 118 S.Ct. 1003, 140 L.Ed.2d 210. Thus the issue about Rule 23 certification should be treated first, "mindful that [the Rule's] requirements must be interpreted in keeping with Article III constraints...." *Amchem, supra,* at 612–613, 521 U.S. 591, 117 S.Ct. 2231, 138 L.Ed.2d 689.

\*10 Id.

Thus, Amchem and Ortiz stand for the proposition that, in cases where a court is presented with class certification and Article III standing issues simultaneously, and the class certification issues are dispositive in that they pertain to statutory standing—i.e. whether a statute authorizes a given party to sue in the first place, the certification issues are

"logically antecedent" to the standing issues and the court may therefore elect to address the certification issues first in the interest of judicial restraint. Under these circumstances, if a court finds that "certification of [a] proposed class [is] improper, the issue of certain class members' standing would [be] moot." *In re Welbutrin XL*, 260 F.R.D. at 153.

Here, however, the Court is presented solely with the issue of whether the named IP Plaintiffs have standing to assert the causes of action in the Indirect CAC, a threshold issue that the Court must address. See Lewis 518 U.S. at 357. Contrary to Ramirez and In re Grand Theft Auto, the "[Supreme] Court's standing cases confirm that a plaintiff must demonstrate standing for each claim he seeks to press." DaimlerChrystler Corp. v. Cuno, 547 U.S. 332, 335, 126 S.Ct. 1854, 164 L.Ed.2d 589 (2006); see also Allen v. Wright, 468 U.S. 737, 752, 104 S.Ct. 3315, 82 L.Ed.2d 556 (1984) ("[T]he standing inquiry requires careful judicial examination of a complaint's allegations to ascertain whether the particular plaintiff is entitled to an adjudication of the particular claims asserted."); Blum v. Yaretsky, 457 U.S. 991, 999, 102 S.Ct. 2777, 73 L.Ed.2d 534 (1982) ("It is not enough that the conduct of which the plaintiff complains will injure someone. The complaining party must also show that he is within the class of persons who will be concretely affected. Nor does a plaintiff who has been subject to injurious conduct of one kind possess by virtue of that injury the necessary stake in litigating conduct of another kind, although similar, to which he has not been subject."). Otherwise, a plaintiff would be able to bring a class action complaint under the laws of nearly every state in the Union without having to allege concrete, particularized injuries relating to those states, thereby dragging defendants into expensive nationwide class discovery, potentially without a good-faith basis. In other words, the plaintiff would have to do "no more than name the preserve on which he intends to hunt." Johnson v. Ga. Highway Express, Inc., 417 F.2d 1122, (5th Cir.1969), overruled on other grounds by Griffin v. Dugger, 823 F.2d 1476 (11th Cir.1987). Accordingly, because the named IP Plaintiff lack standing to assert antitrust violations under the laws of Arizona, the District of Columbia, Hawaii, Illinois, Maine, Minnesota, Nebraska, Nevada, New Mexico, New York, North Carolina, North Dakota, Oregon, South Dakota, Tennessee, Utah, and West Virginia, see Note 10, IP Plaintiffs' claims under those laws are dismissed.

#### C. The Alleged MgO Conspiracy

i. One Conspiracy or Two

\*11 As an initial matter, Defendants maintain that Plaintiffs allegations are confusing to the point where it is impossible to determine whether the alleged conspiracy relates to DBM, CCM, or MgO in general. As a result, Defendants contend that Plaintiffs fail to allege a plausible antitrust conspiracy. This contention is unfounded. While Plaintiffs at times refer to anticompetitive conduct regarding MgO generally, it is clear from the surrounding allegations whether such conduct concerns DBM or CCM. Indeed, as evidenced by their next contention, Defendants have no problem categorizing Plaintiffs' individual allegations as relevant to DBM or CCM.

Moreover, the CACs specifically note at the outset that the term MgO can refer to DBM or CCM. *See* (Direct CAC ¶ 1; Indirect CAC ¶ 1 n. 1).

On that note, Defendants contend that, to the extent that the Court finds that Plaintiffs allege distinct conspiracies regarding DBM and CCM, respectively, the Court should analyze the allegations relating to each conspiracy separately and require that those allegations independently meet the pleading requirements of *Twombly* and *Iqbal*. Plaintiffs counter that they allege a single MgO conspiracy comprised of intertwined and interdependent anticompetitive agreements.

As Plaintiffs point out, it is well-settled that "[t]he character and effect of a conspiracy are not to be judged by dismembering it and viewing its separate parts, but only by looking at it as a whole." Continental Ore Co. v. Union Carbide & Carbon Corp., 370 U.S. 690, 699, 82 S.Ct. 1404, 8 L.Ed.2d 777 (1962); see also In re Fine Paper Antitrust Litig., 685 F.2d 810, 822 (3d Cir.1982) ("a seriatim examination of [ ] claims against each [ ] conspiracy defendant[] as if they were separate lawsuits ... overlook[s] the conspiracy itself."). Defendants contend that the Supreme Court's ruling in Continental Ore is inapposite because that case concerned a monopolistic exclusion conspiracy, as opposed to a price-fixing conspiracy. This contention is remarkably unpersuasive. The very case that Continental Ore cites for the proposition that a court must look to an alleged conspiracy as a whole, *United States v. Patten*, 226 U.S. 525, 33 S.Ct. 141, 57 L.Ed. 333 (1913), concerned a conspiracy to artificially inflate the price of cotton. Furthermore, there is no indication that Continental Ore limited its ruling to conspiracies based on monopolistic exclusion. See 370 U.S. at 699 ("we do not believe that ... liability under the antitrust laws can be measured by any rigid or mechanical formula ..."). Finally, Defendants fail to present, nor does the Court see, a single reason why it would be any less logical or equitable to assess an alleged price-fixing or market allocation conspiracy as a whole than a monopolistic exclusion conspiracy.

Defendants' contention that the Court should analyze Plaintiffs' allegations separately with respect to DBM and CCM because Plaintiffs allege "two different courses of conduct as to the two different products at two different times" (Sumitomo Reply Br., 3) is also unavailing. While it is true that Defendants initially "agreed to fix prices and allocate markets for DBM," ("the DBM Agreement") and subsequently agreed to allocate the domestic CCM market to Premier ("the CCM Agreement"), (id.), those agreements are not mutually exclusive. To the contrary, the CCM Agreement is dependent on the DBM Agreement, and vice versa. See In re Vitamins Antitrust Litig., 320 F.Supp.2d 1, 16 (D.D.C.2004) (recognizing the potential "interdependency between various branches of a common conspiracy."). Specifically, Defendants entered into the CCM Agreement in order to restore and maintain the DBM Agreement after Premier broke that agreement due to Sumitomo and YAS's attempt to enter the domestic CCM market. Consequently, the absence of one eliminates the consideration for the other. Moreover, "[h]orizontal antitrust conspiracies commonly include sellers in more than one relevant market." In re Vitamins Antitrust Litig., No. MISC 99-197, 2000 WL 1475705, at \*10 (D.D.C. May 9, 2000). Accordingly, the Court will treat Plaintiffs CACs as alleging a single conspiracy not to compete in the sale of two forms of MgO.

# ii. The Necessity of Allegations Regarding the MgO Market

\*12 Defendants argue that Plaintiffs fail to allege an unlawful price-fixing and market allocation conspiracy because they do not set forth relevant market conditions and Sumitomo's, YAS's, and Premier's relative market power indicating that they plausibly could have fixed the price of DBM and allocated the domestic DBM and CCM markets. Plaintiffs argue that they are alleging per se violations of Section 1 of the Sherman Act and therefore "Defendants' arguments concerning market power and relevant markets are legally irrelevant." (DP Pl's. Br., 12.)

"Section 1 of the Sherman Act provides: Every contract, combination in the form of trust or otherwise, or conspiracy, in restraint of trade or commerce among the several States, or with foreign nations, is declared to be illegal." *In re Ins. Brokerage Antitrust Litig.*, 618 F.3d 300, 314 (3d Cir.2010)

(quoting 15 U.S.C. § 1). "[T]his statutory language imposes two essential requirements on an antitrust plaintiff." *Id.* "First, the plaintiff must show that the defendant was a party to a contract, combination ... or conspiracy." *Id.* at 315 (quotation and citation omitted). This requires the plaintiff to demonstrate "some form of concerted action" indicating a "unity of purpose or a common design and understanding or a meeting of the minds or a conscious commitment to a common scheme." *Id.* (quotations and citations omitted).

Second, "the plaintiff must show that the conspiracy to which the defendant was a party imposed an unreasonable restraint on trade ." *Id.* (quotation and citation omitted). "[T]he usual standard applied to determine whether a challenged practice unreasonably restrains trade is the so-called rule of reason." *Id.* (quotation and citation omitted). "[U]nder a rule-of-reason analysis, the plaintiff bears the initial burden of showing that the alleged [agreement] produced an adverse, anticompetitive effect within the relevant geographic market." *Id.* (quotation and citation omitted). "[S]uccessful attempts to meet this burden typically include a demonstration of defendants' market power, as a judgment about market power is [a] means by which the effects of the [challenged] conduct on the market place can be assessed." *Id.* at 315–16 (quotation and citations omitted).

"If the plaintiff carries this burden, the court will need to decide whether the anticompetitive effects of the practice are justified by any countervailing pro-competitive benefits." *Id.* However, "Judicial experience has shown that some classes of restraints" almost never have "redeeming competitive benefits," and therefore a court need not apply the rule of reason analysis. *Id.* Instead, they are "subject to a 'per se' standard." *Id.* "Paradigmatic examples are horizontal agreements among competitors to fix prices or to divide markets." *Id.* (quotation and citation omitted). If a plaintiff's allegations "fall into one of the recognized classes," an unreasonable restraint on trade is "conclusively presumed" and therefore "plaintiffs are relieved of the obligation to define a market and prove market power." *Id.* (citations omitted).

\*13 As discussed below, Plaintiffs sufficiently allege that Defendants entered into (1) a horizontal agreement to fix prices in and allocate shares of the domestic DBM market and (2) a horizontal agreement to allocate the domestic CCM market to Premier. Accordingly, Plaintiffs assert per se antitrust violations that do not require allegations regarding

the nature of the domestic DBM and CCM markets or Defendants' power within those markets. 12

This also disposes of Sumitomo's contention that the Court should consider "certain relevant facts" noted in *Animal Science Prods., Inc. v. China Nat'l Metals & Minerals*, 596 F.Supp.2d 842 (D.N.J.2008) regarding the domestic DBM and CCM markets. (Sumitomo (DP Pl.'s) Br., 4.)

#### iii. The DBM Agreement

Defendants argue that Plaintiffs' allegations of an agreement to fix prices in and allocate shares of the domestic DBM market are facially insufficient because (1) they fail to provide the substance of the agreement, (2) they fail to rule out potentially alternative, lawful explanations for such an agreement, and (3) their "factual narrative is inherently implausible." (Sumitomo (DP Pl's.) Br., 15.) Plaintiffs argue that their allegations of a price-fixing and market allocation agreement are sufficient because (1) they "explicitly state who was conferring with whom about MgO pricing, markets and customers" (DP Pl's. Br., 15.), and (2) Defendants' arguments regarding the inherent plausibility of the alleged conspiracy implicate factual questions that are not properly resolved on a motion to dismiss.

Defendants' contention that Plaintiffs' allegations are inadequate because they "fail to disclose the actual substance of the alleged conversations or agreements" (Sumitomo (DP Pl's.) Br., 14) is unavailing. Twombly does not require detailed allegations regarding the specific nature of a price-fixing or market allocation agreement; rather, "stating such a claim requires a complaint with enough factual matter (taken as true) to suggest that an agreement was made." 550 U.S. at 556. Put another way, a complaint "simply calls for enough fact to raise a reasonable expectation that discovery will reveal evidence of an illegal agreement." Id. Requiring Plaintiffs to set forth the full details of an antitrust conspiracy at this stage of the litigation would present an onerous burden because "in antitrust cases, [ ] the proof is largely in the hands of the alleged conspirators." In re Neurontin Antitrust Litig., No. 02-1390, 2009 WL 2751029, at \*7 (D.N.J. Aug.28, 2009) (quoting Hosp. Building Co. Trustees of Rex Hosp., 425 U.S. 738, 96 S.Ct. 1848, 48 L.Ed.2d 338 (1976)).

Here, Plaintiffs allege that (1) a significant portion of DBM consumed in the United States comes from China; (2) during the Class Period, Premier and Sumitomo bought nearly all Chinese DBM available for purchase and resold

it to their customers in the United States; (3) Mr. Ahl of Premier "regularly called" Mr. Sumikawa of YAS "to discuss fixing Premier's and Sumitomo's [DBM] prices and allocating their respective MgO accounts in the U.S" (Direct CAC ¶ 34; Indirect CAC ¶ 42); (4) these market allocation and price-fixing schemes were implemented by Mr. Ahl and his successors at Premier and Mr. Wakisama of Sumitomo; (5) at the 2004 Tulsa meeting, Mr. Akiyama recounted to Mr. Sumikawa "multiple discussions" between him and Mr. Ahl to set DBM prices and allocate DBM markets "and ensure that Sumitomo was maintaining its agreement with Premier to fix [DBM] prices and allocate [DBM] markets," (Direct CAC ¶ 40; Indirect CAC ¶ 49); and (5) when Mr. Vannorsdel allegedly "expressed concern about compromising his relationship with Premier by helping facilitate Sumitomo and YAS's involvement" in the CCM market, Mr. Akiyama responded, "'Don't be concerned because we [Sumitomo] talk with Premier on a daily basis to set prices and to discuss what accounts they can have.' "(Direct CAC ¶ 41; Indirect CAC ¶ 50.)

\*14 These allegations plausibly suggest that Defendants entered into an agreement to fix prices in and allocate shares of the domestic DBM market, the specifics of which can be reasonably expected to be revealed in discovery. Plaintiffs state (1) the subject of the alleged agreement, (2) the parties to the agreement and the specific individuals that discussed and implemented the agreement, and (3) the context in which the agreement arose. This is sufficient to withstand a motion to dismiss.

Defendants' contention that Plaintiffs fail to assert a plausible antitrust conspiracy because their allegations could, in fact, refer to a lawful vertical agreement between Sumitomo and Premier to fix prices for DBM whereby Sumitomo purchases DBM from Premier as a reseller, is irrelevant. At the pleading stage, Plaintiffs need only set forth allegations that create an inference of an unlawful agreement, *Twombly*, 550 U.S. at 556, which, as previously discussed, they have done; they need not set forth allegations tending to rule out potential alternative explanations. <sup>13</sup>

This is to be distinguished from the requirement to plead plus factors to rule out independent action "when a plaintiffs' claims of conspiracy rest on parallel conduct," *In re Ins. Brokerage*, 618 F.3d at 323, which is discussed below regarding the alleged CCM Agreement. Plaintiffs need not assert plus factors to establish the plausibility of the DBM Agreement because they set forth direct

allegations of that agreement. *See In re Ins. Brokerage*, 618 F.3d at 323 ("Allegations of direct evidence of an agreement, if sufficiently detailed, are independently adequate.").

Finally, Defendants' contention that the alleged DBM Agreement is "inherently implausible" in that, on the one hand, Sumitomo was allegedly worried about retaliatory action by Premier for attempting to enter the CCM market and, on the other hand, "could give credible assurances to the Vannorsdels that it could shield them from Premier['s] retaliation because of [Sumitomo's] 'daily' contact with Premier," (Sumitomo (DP Pl.'s) Br., 15) is similarly irrelevant because it asks the Court to improperly assess the merits of Plaintiffs' allegations. 14 See Aktieselskabet AF 21. November 2001 v. Fame Jeans Inc., 525 F.3d 8, 17 (D.C.Cir.2008) ("Twombly was concerned with the plausibility of an inference of conspiracy, not with the plausibility of a claim. A court deciding a motion to dismiss must not make any judgment about the probability of the plaintiff's success ... the court must assume that all the allegations in the complaint as true (even if doubtful in fact)" (quotations and citations omitted)). Thus, Plaintiffs have sufficiently alleged an unlawful agreement among Defendants to fix prices in and allocate shares of the domestic DBM market.

Moreover, there is nothing "inherently implausible" about Sumitomo's attempt to assuage the Vannorsdels' concern about Premier's potential retaliation by stating that it speaks with Premier on a daily basis to set DBM prices and allocate shares of the DBM market. It is certainly plausible that Sumitomo was aware of the risk of retaliation by Premier but believed it could "enter the [CCM] market discreetly" (Direct CAC ¶ 39; Indirect CAC ¶ 48) because Premier's attention was focused on maintaining their agreement in the DBM market.

#### iv. The CCM Agreement

Defendants contend that Plaintiffs fail to allege the existence of an unlawful agreement to allocate the domestic CCM market to Premier because (1) they merely allege parallel conduct that does not indicate concerted action, (2) there are obvious alternative explanations for Sumitomo's and YAS's decision not to enter the CCM market, and (3) they fail to establish that Defendants were competitors in the CCM market. Plaintiffs counter that they are not relying on parallel conduct but rather direct admissions of an agreement among Defendants to allocate the domestic CCM market to Premier, and therefore Defendants' proffered alternative explanations are irrelevant.

As previously discussed, Section 1 of the Sherman Act "does not prohibit [all] unreasonable restraints of trade ... but only restraints effected by a contract, combination, or conspiracy." Twombly, 550 U.S. at 553 (quotation and citation omitted). This is because seemingly anticompetitive conduct may be just as "consistent with conspiracy ... [as] with a wide swath of rational and competitive business strategy unilaterally prompted by common perceptions of the market." Id. at 554 (citation omitted). Accordingly, "[t]he crucial question is whether the challenged anticompetitive conduct stem[s] from independent decision or from an agreement, tacit or express." Id. at 553 (quotation and citation omitted). "Hence, when allegations of parallel conduct are set out in order to make a § 1 claim, they must be placed in a context that raises a suggestion of a preceding agreement, not merely parallel conduct that could just as well be independent action." Id. at 557.

\*15 This is usually accomplished by pleading one or more "plus factors" that "indicate the existence of an actionable agreement." *In re Ins. Brokerage*, 618 F.3d at 321. While "[t]here is no finite set of such criteria," the Court of Appeals has identified "at least three such plus factors: (1) evidence that the defendant had a motive to enter into a[] conspiracy; (2) evidence that the defendant acted contrary to its interests; and (3) evidence implying a traditional conspiracy." *Id.* at 321–22 (quotations and citation omitted).

Here, Plaintiffs' allegations suggest an agreement among Defendants to allocate the CCM market to Premier. Plaintiffs allege that (1) representatives from Sumitomo and YAS met with others at a Tulsa hotel, in the summer of 2004, to discuss entering the domestic CCM market in order to fill Sumitomo's barge capacity; (2) Premier discovered their plan to enter the domestic CCM market and retaliated by lowering DBM prices; and (3) as a result, Sumitomo and YAS agreed with Premier to remain out of the CCM market.

To be sure, contrary to Plaintiffs' contentions, these allegations do not amount to a direct admission of an unlawful agreement to allocate the CCM market to Premier; taken in isolation, they merely amount to parallel conduct plus a conclusory allegation of an agreement. Placing these allegations in the context of the CACs as a whole, however, Plaintiffs successfully demonstrate the first plus factor—that Sumitomo and YAS had a motive to enter into an unlawful agreement with Premier to stay out of the domestic CCM market—and provide a plausible context for that agreement.

As previously discussed, Sumitomo and YAS maintained an agreement with Premier to fix prices in and allocate shares of the domestic DBM market. As a result, as the CACs indicate, Sumitomo and YAS wanted to enter the CCM market undetected so that they could continue to maintain their agreement with Premier in the DBM market. When Premier discovered their plans and, in response, cut prices in the DBM market, Sumitomo and YAS agreed with Premier to stay out of the CCM market with the motive of restoring and maintaining their agreement in the DBM market.

In this context, Defendants' alternative explanations that a profit-maximizing entity could independently decide not to enter a market in which (1) it remained unfamiliar with the product and its customers and (2) the dominant player recently cut prices are by no means "obvious" or "more plausible" (Sumitomo (DP Pl's.) Br., 18) than an illegal agreement to stay out of the CCM market and therefore do not provide a basis for dismissal. At the pleading stage, "a claim of conspiracy predicated on parallel conduct should be dismissed if common economic experience, or the facts alleged in the complaint itself, show that independent selfinterest is an obvious alternative explanation for defendants' common behavior." In re Ins. Brokerage, 618 F.3d at 326. Plaintiffs' allegations need not rule out all potential alternative explanations. See Starr v. Sony BMG Music Entertainment, 592 F.3d 314, 352 (2d Cir.2010) ("Although the Twombly court acknowledged that for purposes of summary judgment a plaintiff must present evidence that tends to exclude the possibility of independent action, it specifically held that, to survive a motion to dismiss, plaintiffs need only enough factual matter (taken as true) to suggest that an agreement was made" (quotations and citations omitted)).

\*16 Finally, Sumitomo's argument that Plaintiffs fail to allege a plausible agreement to allocate the CCM market to Premier because there is no indication that Defendants were actual or potential competitors in the CCM market is unavailing. Sumitomo specifically contends that Plaintiffs must establish that it had the intent and capability of entering the CCM market as a competitor in order to allege a plausible agreement among Defendants to allocate the CCM market to Premier. However, the authority cited by Sumitomo provides little support for this contention. *See Palmer v. BRG of Georgia, Inc.*, 498 U.S. 46, 49–50, 111 S.Ct. 401, 112 L.Ed.2d 349 (1990) (parties need not have competed in the same territorial market to unlawfully allocate that market); *Andrx Pharm, Inc. v. Bioval Corp., Int'l*, 256 F.3d 799, 806–07 (D.C.Cir.2001) (potential competitor must show background

and experience in new market, financial capability to enter market, and affirmative steps toward entry in order to establish injury-in-fact for standing to sue under Section 4 of the Clayton Act); *Engine Specialities, Inc. v. Bombardier Ltd.*, 605 F.2d 1, 9 (1st Cir.1979) (to sustain jury finding of unlawful horizontal market allocation agreement among potential competitors, there must have been sufficient support in the record to establish that potential competitors had the "necessary desire, intent, and capability to enter the market").

To be sure, the Court of Appeals has generally recognized that the existence of an unlawful horizontal agreement to allocate a given market must occur among competitors or potential competitors in that market:

An agreement among persons who are not actual or potential competitors in a relevant market is for Sherman Act purposes *brutum fulmen* ... To some extent, of course, a horizontal agreement tends to define the relevant market, for it tends to show that the parties to it are at least potential competitors. If they were not, there would be no point to such an agreement. Thus its very existence supports an inference that it would have an effect in a relevant market. Where, ... however, the disputed issue is the existence or scope of the alleged horizontal agreement that is to be inferred from circumstantial evidence, the first inquiry must be whether or not each firm alleged to have been a party to it was an actual or potential competitor in that market.

United States v. Sargent Elec. Co., 785 F.2d 1123, 1127 (3d Cir.1986) (reversing dismissal of indictment on double jeopardy grounds). However, Sumitomo fails to present, nor is the Court aware of, any authority requiring a purchaser plaintiff to specifically establish, at the pleading stage, that the parties to a horizontal agreement to allocate a given market were competitors or potential competitors in that market. To require Plaintiffs, pre-discovery, to establish Sumitomo's background and experience in the CCM market, its financial capability to enter that market, and the specific steps taken by Sumitomo to enter it, would be overly onerous, as much of this information is likely to be exclusively in the hands of Sumitomo. Thus, Plaintiffs have sufficiently alleged an unlawful agreement among Defendants to allocate the domestic CCM market to Premier.

In any event, Plaintiffs allege Sumitomo's motive for entering the CCM market (filling excess barge capacity), and certain steps taken to enter that market (meeting with the Vannorsdels in Tulsa).

# v. YAS' Involvement in the Alleged Conspiracy

\*17 YAS separately argues that Plaintiffs fail to establish its participation in the alleged conspiracy because they fail to show that it came to a meeting of the minds with Sumitomo and Premier to (1) fix prices in and allocate shares of the domestic DBM market and (2) allocate the domestic CCM market to Premier. Plaintiffs counter that (1) they have set forth direct allegations indicating YAS's knowledge and participation in the alleged conspiracy, and (2) YAS need not have played the same role in the conspiracy, maintain the same motives as Sumitomo or Premier for participating in it, or sell MgO to be held liable.

16 Citing to Toledo Mack Sales & Serv. v. Mack Trucks, Inc., 530, F.3d 204 (3d Cir.2008), YAS further argues that Plaintiffs' failure to establish that YAS occupies the same level as Sumitomo and Premier on the MgO supply chain "precludes per se treatment of YAS' alleged antitrust violations." (YAS Br., 4 n. 5.) This argument misses the mark. While Toledo Mack noted that, "[i]n contrast to horizontal price-fixing agreements between entities at the same level of a product's distribution chain, the legality of a vertical agreement that imposes a restriction on the dealer's ability to sell the manufacturer's product is governed by the rule of reason," and that "[t]he rule of reason analysis applies even when ... the plaintiff alleges that the purpose of the vertical agreement between a manufacturer and its dealers is to support illegal horizontal agreements between multiple dealers," 530 F.3d at 225 (citation omitted), Plaintiffs do not allege YAS' arrangement with Sumitomo to source Chinese magnesite and MgO constitutes an unlawful vertical agreement to support a horizontal conspiracy between Sumitomo and Premier. Rather, Plaintiffs allege that YAS participated directly with Sumitomo and Premier in the alleged horizontal conspiracy to fix prices in and allocate shares of the DBM market and allocate the CCM market to Premier. Moreover, "[t]he law is settled that where an upstream supplier participates in a conspiracy involving horizontal competitors, it is proper to analyze the entire restraint as one of horizontal price-fixing." In re Mercedez-Benz, 157 F.Supp.2d at 362.

As previously discussed, to hold YAS or any other Defendant liable, Plaintiffs must set forth allegations suggesting that YAS maintained "unity of purpose or a common design and understanding or a meeting of minds or a conscious commitment to a common scheme" with Sumitomo and Premier to (1) fix prices in and allocate shares of the domestic DBM market, and (2) allocate the CCM market to Premier. *In re Ins. Brokerage*, 618 F.3d at 315 (quotations and citation

omitted). This does not require a showing that YAS knew of or participated in every transaction in furtherance of or related to the alleged conspiracy. See TV Signal Co. of Aberdeen v. American Tel. & Tel. Co., 462 F.2d 1256, 1259 (8th Cir.1972) ("Although knowledge is implicit in the requirement of unity of purpose, no case of which we are aware requires that each party to a conspiracy knows of each transaction encompassed by the conspiracy in order to be held accountable therefore."); In re Vitamins Antitrust Litig., 320 F.Supp.2d 1, 15 (D.D.C.2004) ("Although Plaintiffs must show that each Defendant had knowledge of an agreement as to the overall conspiracy, they need not show (1) evidence of a formal agreement, or (2) knowledge, on behalf of the Defendant, of every detail of the alleged conspiracy."); In re Mercedez-Benz, 157 F.Supp.2d at 375 ("That a particular defendant may or may not have joined in a specific overt act in furtherance of the conspiracy ... does not affect its status as a conspirator."). On the other hand, "knowledge alone [of the conspiracy] is not sufficient" to hold it liable. In re Vitamins, 320 F.Supp.2d at 16. Plaintiffs must therefore set forth allegations suggesting that YAS (1) had knowledge of the conspiracy to fix prices in and allocate shares of the domestic DBM market, and allocate the CCM market to Premier, and (2) intended to join that conspiracy. Id. "[A] a party progresses form mere knowledge of an endeavor to intent to join it when there is 'informed and interested cooperation, stimulation, instigation. And there is also a stake in the venture which, even if it may not be essential, is not irrelevant to the question of conspiracy." "Id. (quoting Direct Sales Co. v. United States, 319 U.S. 703, 713, 63 S.Ct. 1265, 87 L.Ed. 1674 (1943)).

## 1. The DBM Agreement

Plaintiffs allege that Mr. Sumikawa of YAS (1) facilitates Sumitomo's purchases of Chinese DBM for resale in the domestic DBM market, (2) received regular phone calls from Mr. Ahl of Premier "to discuss fixing Premier's and Sumitomo's [DBM] prices and allocating their respective [DBM] accounts in the U.S," (Direct CAC ¶ 34; Indirect CAC ¶ 42), and (3) attended the 2004 Tulsa meeting where (i) Mr. Akiyama of Sumitomo recounted to him "multiple discussions" between him and Mr. Ahl to set DBM prices and allocate DBM markets "and ensure that Sumitomo was maintaining its agreement with Premier to fix [DBM] prices and allocate [DBM] markets," (Direct CAC ¶ 40; Indirect CAC ¶) and (ii) it was revealed that Sumitomo communicates with Premier on a daily basis fix prices and allocate accounts. These allegations create a plausible inference that YAS had knowledge of an agreement to fix prices in and allocate shares of the domestic DBM market and the intent to join it. Accepting Plaintiff's allegations as true and making all reasonable inferences in their favor, YAS' facilitation of Sumitomo's DBM purchasing indicates a plausible stake in the DBM Agreement, while its receipt of phone calls to discuss the Agreement and attendance at a meeting at which it was revealed indicates that YAS had knowledge of the DBM Agreement and that it engaged in informed and interested cooperation.

\*18 Citing to In re Elevator Antitrust Litig., 502 F.3d 47, 50 (2d Cir.2007) and Hinds County, Mississippi v. Wachovia Bank N.A., 620 F.Supp.2d 499, 518 (S.D.N.Y.2009), YAS argues that these allegations should be "discounted" because they amount to mere "averments of agreements made at some unidentified place and time." (YAS Br., 4.) In re Elevator Antitrust Litig. concerned a list of "basically every type of conspiratorial activity that one could imagine ... in entirely general terms without any specification of any particular activities by any particular defendant." 502 F.3d at 50. Similarly, Hinds County dealt with conclusory allegations of "' 'per se illegal horizontal communications' in support of [an] alleged conspiracy." 620 F.Supp.2d at 518. Here, in contrast, Plaintiffs allege (1) the way in which YAS participates with Sumitomo—a member of the conspiracy—in the domestic DBM market, (2) phone calls from Premier—another party to the conspiracy-to YAS to discuss fixing prices in and allocating shares of the domestic DBM market, and (3) YAS's attendance at a meeting where Sumitomo—its partner in the domestic DBM market-recounted to YAS discussions in which it set prices in and allocated shares of the domestic DBM market with Premier. These allegations, do not amount to a mere "list of theoretical possibilities," In re Elevator Antitrust Litig., 502 F.3d at 50, or "require the Court to assume the existence of the conspiracy." Hinds County, 620 F.Supp.2d at 518. Rather, they make the alleged conspiracy more plausible.

YAS further argues that "it is wholly implausible that [it] (a minor player that was not itself a manufacturer, importer or seller 17) would have discussed fixing Premier's and Sumitomo's [DBM] prices," particularly since Plaintiffs fail to "allege that YAS had any ability to influence (let alone) dictate Sumitomo's [DBM] prices, nor which customers Sumitomo dealt with." (YAS Br., 5.) As previously discussed, this line of argument is not only improper at the pleading stage—where the Court must accept Plaintiffs' allegations as true—it is also unpersuasive. There is nothing "wholly implausible" about YAS participating in discussions to fix

prices in and allocate shares of the domestic DBM market. Sumitomo was only able to participate in the domestic DBM market in the first place due to YAS's relationship with Chinese mines from which Sumitomo could purchase DBM and magnesite. Consequently, it is certainly plausible that YAS could participate in discussions with co-conspirators to fix prices and allocate shares of the DBM market.

Citing to Howard Hess Dental Laboratories Inc. v. Dentsply Intern., Inc., 424 F.3d 363 (3d Cir.2005), YAS also argues that Plaintiffs' failure to allege that it sold DBM or CCM requires its dismissal from this case as a matter of law. While that case notes the well-settled proposition that only direct purchasers may recover damages in federal antitrust suits, it by no means indicates that only a seller of the product in question may be found liable in a Section 1 conspiracy. As previously discussed, YAS need not have participated in a particular act in furtherance of the conspiracy to be held liable.

# 2. The CCM Agreement

Plaintiffs' allegations suggesting an agreement among Sumitomo and Premier to allocate the CCM market to Premier apply with equal force to YAS. As previously discussed, Plaintiffs allege that (1) Sumitomo and YAS met with others at a Tulsa hotel, in the summer of 2004, to discuss entering the domestic CCM market in order to fill Sumitomo's barge capacity; (2) Premier discovered their plan to enter the domestic CCM market and retaliated by lowering DBM prices to keep Sumitomo and YAS out of the CCM market; and (3) as a result, Sumitomo and YAS agreed with Premier to remain out of the CCM market.

\*19 YAS argues that these allegations are conclusory because they "provide [ ] no details whatsoever about YAS's participation in this alleged agreement, including what role it is alleged to have played." (YAS Br., 7.) At the pleading stage, however, Plaintiffs need not allege the specific nature of YAS's or any other Defendant's participation in the agreement to allocate the CCM market to Premier. See In re Static Random Access Memory (SRAM) Antitrust Litig., 580 F.Supp.2d 896, 904 (N.D.Cal.2008) ("Although Plaintiffs will need to provide evidence of each Defendants' participation [at summary judgment] ... they now only need to make allegations that plausibly suggest that each Defendant participated in the alleged conspiracy."). As previously discussed, Plaintiffs must set forth allegations suggesting that YAS had knowledge of the agreement and the intent to join it. Plaintiffs' allegations that YAS, as Sumitomo's partner in the domestic MgO market, (1) attended a meeting to arrange

for Sumitomo to enter the domestic CCM market and (2) subsequently agreed with Sumitomo and Premier to allocate that market to Premier in order to maintain their agreement to fix prices and allocate shares of the domestic DBM market, do just that.

Finally, like Sumitomo, YAS argues that it cannot be held liable for the alleged agreement to allocate the domestic CCM market to Premier because Plaintiffs fail to establish that YAS was an actual or potential competitor in that market. For the reasons discussed in Point IICiv, at the pleading stage, Plaintiffs, as purchasers, need not establish that YAS was an actual or potential competitor in the CCM market in order to allege its participation in a horizontal conspiracy. Furthermore, YAS's (1) role in facilitating Sumitomo's purchase of Chinese DBM and (2) attendance at the 2004 Tulsa meeting where it, Sumitomo, and the Vannorsdels discussed entering into the CCM market, suggests that YAS intended to participate with Sumitomo in the CCM market in the same way as they had been participating in the DBM market. Thus, Plaintiffs have set forth allegations plausibly suggesting that YAS participated in an agreement to allocate the CCM market to Premier.

### D. Statute of Limitations and Fraudulent Concealment

Actions brought under the Clayton Act are subject to a four-year statute of limitations. 15 U.S.C. § 15b. In an antitrust conspiracy that continues over a period of years, each overt act in furtherance thereof that injures the plaintiff —for example, the selling of a price-fixed product—starts the statute of limitations period running for that particular act. Klehr v. A.O. Smith Corp., 521 U.S. 179, 189, 117 S.Ct. 1984, 138 L.Ed.2d 373 (1997); see also Zenith Radio Corp. v. Hazeltine Research, Inc., 401 U.S. 321, 338, 91 S.Ct. 795, 28 L.Ed.2d 77 ("Generally, a cause of action accrues and the statute begins to run when a defendant commits an act that injures a plaintiff's business" (citations omitted)). However, "the commission of a separate new overt act generally does not permit the plaintiff to recover for the injury caused by old overt acts outside the limitations period." Klehr, 521 U.S. at 190 (citations omitted).

\*20 Defendants argue that Plaintiffs' federal antitrust claims are barred by the applicable four-year statute of limitations. Specifically, Defendants contend that Plaintiffs (1) fail to allege overt acts in furtherance of the alleged conspiracy that occurred after 2004 and (2) fail to plead fraudulent concealment with particularity to otherwise toll the statute of limitations. Plaintiffs do not dispute that they fail to allege

overt acts after 2004, but maintain that they plead fraudulent concealment with the requisite particularity to toll the statute of limitations.

The equitable doctrine of fraudulent concealment applies to every federal statute of limitations. *Holmberg v. Armbrecht*, 327 U.S. 392, 397, 66 S.Ct. 582, 90 L.Ed. 743 (1946). To toll a statute of limitations through fraudulent concealment, a plaintiff must show "(1) an affirmative act of concealment; (2) which misleads or relaxes the plaintiff's inquiry, who (3) exercised due diligence in investigating his cause of action ." *In re Lower Lake Erie Iron Ore Antitrust Litig.*, 998 F.2d 1144, 1178–79 (3d Cir.1993) (citation omitted). In addition, allegations of fraudulent concealment must be pled with particularity in accordance with Federal Rule of Civil Procedure 9(b). *In re Mercedes–Benz*, 157 F.Supp.2d at 368.

However, "Rule 9[ (b) ] does not require plaintiffs to plead facts that, by the nature of the alleged fraud, are within the defendants' control." Id. (citing In re Craftmatic Secs. Litig., 890 F.2d 628, 645 (3d Cir.1989)). Indeed, "[c]ourts must be sensitive to the fact that [a rigid] application of Rule 9(b) prior to discovery may permit sophisticated defrauders to successfully conceal the details of their fraud." In re Craftmatic, 890 F.2d at 645 (quotation and citation omitted). "Thus, courts have relaxed the rule when factual information is peculiarly within the defendant's knowledge or control." Id. Accordingly, under the more flexible application of Rule 9(b), Plaintiffs need not allege the specific information that is exclusively within Defendants' knowledge or control. See id. at 646. However, Plaintiffs must allege facts suggesting fraudulent concealment and "why additional information lies exclusively within the defendants' control." Id.

As discussed fully below, Plaintiffs fail to satisfy each element of fraudulent concealment, thus requiring dismissal of their federal antitrust claims as time-barred. However, the Court will grant Plaintiffs leave to amend their allegations of fraudulent concealment to equitably toll the statute of limitations. <sup>18</sup>

IP Plaintiffs' state antitrust law claims similarly require dismissal for failure to establish fraudulent concealment, as their applicable statutes of limitations range from three to six years. *See* Ariz.Rev.Stat. Ann. § 44–1410(A) (Arizona) (2011) (four years); Cal. Bus. & Prof.Code § 16750.1 (2011) (California) (four years); D.C.Code § 28–4511(b) (2011) (four years); Haw.Rev.Stat. § 480–24(a) (2010) (Hawaii) (four years); Ill. Comp. Stat.

ch. 740, § 10/7(2) (2010) (four years); Iowa Code § 553.16 (2011) (Iowa) (four years); Four B Corp. v. Daicel Chem. Indus., Ltd., 253 F.Supp.2d 1147, 1156 (D.Kan.2003) (Kansas) (three years) (citing Kan. Stat. Ann. § 60-512(2) (2010)); McKinnon v. Honeywell Int'l, Inc., 977 A.2d 420, 424 (Me.2009) (Maine) (six years) (citing Me.Rev.Stat. Ann. tit. 14 § 752 (2008)); Mich. Comp. Laws § 445.781 (2010) (Michigain) (four years); Am. Computer Trust Leasing v. Jack Farrell Implement Co., 763 F.Supp. 1473, 1491 n. 21 (D.Minn.1991) (Minnesota) (four years) (citing Minn.Stat. § 325D.64 (subdiv .1) (2010)); Miss.Code Ann. § 15–1–49(1) (2010) (three years); Neb.Rev.Stat. § 25–206 (2010) (Nebraska) (four years); Nev.Rev.Stat. § 598A.220(2)(a) (2010) (four years); N.H.Rev.Stat. § 356:12(II) (1973) (New Hampshire) (four years); N.M. Stat. § 57-1-12(B) (1978) (New Mexico) (four years); N.Y. Gen. Bus. Law § 340(5) (2004) (New York) (four years); N.C. Gen.Stat. § 75–16.2 (2010) (North Carolina) (four years); N.D. Century Code § 51-08.1-10(2) (1987) (four years); Or.Rev.Stat. § 646.800(2) (1975) (Oregone) (four years); S.D. Codified Laws § 37-1-14.4 (1975) (South Dakota) (four years); State ex rel. Leech v. Levi Strauss & Co., No. 79-722-III, 1980 WL 4696, at \*3 (Tenn.Ch. Sept.25, 1980) (Tennessee) (three years) (citing Tenn. Stat. § 28–3–105(3) (2011)); Utah Code § 76–10–925(2) (1979) (Utah) (four years); Vt. Stat. Ann. tit. 12, § 511 (2010) (Vermont) (six years); W. Va.Code § 47-18-11 (1978) (West Virginia) (four years); Wis. Stat. § 133.18(2) (2011) (Wisconsin) (six years). However, to the extent that IP Plaintiffs sufficiently amend their allegations to establish fraudulent concealment of their federal antitrust claims, they will also have established fraudulent concealment of their state law antitrust claims. See Note 9.

# i. Affirmative Acts of Concealment

Defendants argue that (1) Plaintiffs fail to sufficiently allege affirmative acts of concealment and (2) their allegations that the MgO conspiracy is self-concealing cannot satisfy the first element of fraudulent concealment. Plaintiffs contend that they have alleged (1) a self-concealing conspiracy that satisfies the first element of fraudulent concealment, or, (2) in the alternative, affirmative acts of concealment committed by Defendants.

Defendants further argue that Sumitomo's alleged admission to the Vannorsdels of the DBM Agreement cuts against their fraudulent concealment allegations. This is unpersuasive because the admission in no way put Plaintiffs on notice of their claims during the limitations period. See Emerson Elec. Co. v. Le Carbon

Lorraine, SA, 500 F.Supp.2d 437, 448 (D.N.J.2007) ("Where fraudulent concealment of a federal antitrust claim has been shown, the four-year federal statute of limitations begins anew from the time the plaintiff knew or should have known of the existence of the federal claim." (quotations and citations omitted)).

\*21 The Court of Appeals has yet to define what constitutes an affirmative act of concealment in antitrust cases. However, courts have generally taken two distinct views. In re Mercedez-Benz, 157 F.Supp.2d at 368. The first requires a plaintiff to show one or more affirmative acts to conceal an antitrust conspiracy that are wholly extrinsic to the conspiracy itself. See, e.g., Colorado v. Western Paving Constr. Co., 630 F.Supp. 206, 2010 (D.Colo.1986), aff'd en banc by an equally divided court, 841 F.2d 1025 (10th Cir.1988), cert. denied, 488 U.S. 870, 109 S.Ct. 179, 102 L.Ed.2d 148 (1988). The second also requires a plaintiff to show one or more affirmative acts of concealment, but those acts may be part and parcel to, or in furtherance of, the conspiracy. Supermarket of Marlington, Inc. v. Meadow Gold Dairies, Inc., 71 F.3d 119, 122 (4th Cir.1995) (citing Texas v. Allen Constr. Co., 851 F.2d 1526, 1532 (5th Cir.1988)). The Court finds the first view to be overly restrictive in this case. In a conspiracy involving price-fixing, "it is virtually impossible to distinguish between acts in furtherance of the conspiracy and acts designed to maintain the conspiracy's secrecy because the conspiracy's success is often contingent upon its ability to avoid detection by regulators and purchasers." In re Aspartame Antitrust Litig., No. 06–1732, 2007 WL 5215231, at \*5 (E.D.Pa. Jan.18, 2007); See also In re Mercedez-Benz, 157 F.Supp.2d at 372 ("secrecy is [the] natural lair" of a pricefixing conspiracy).

Several courts, including those in this Circuit, have found that a plaintiff may avoid the affirmative act requirement altogether in cases where an antitrust conspiracy is "inherently self-concealing." See, e.g., In re Aspartame, 2007 WL 5215231, at \*5; In re Nine West Shoes Antitrust Litig., 80 F.Supp.2d 181, 192 (S.D.N.Y.2000); In re Mercedez-Benz, 157 F.Supp.2d at 371; Pennsylvania Milk Indus. Mgmt. Corp., 812 F.Supp. 500 (E.D.Pa.1992); Bethlehem Steel Corp. v. Fischbach & Moore, Inc., 641 F.Supp. 271, 273–74 (E.D.Pa.1986). However, the definition of a selfconcealing antitrust conspiracy, particularly one that involves price-fixing, remains nebulous. The In re Mercedez-Benz court held that a self-concealing antitrust conspiracy is one where "concealment is so intertwined with the conspiracy as a whole that the equitable foundations of the fraudulent concealment doctrine require the limitations period to be tolled." 157 F.Supp.2d at 371. Other courts maintain that all properly alleged price-fixing conspiracies are inherently self-concealing. *See, e.g., In re Issuer Plaintiff Initial Public Offering Antitrust Litig.*, No. 00–7804, 2004 WL 487222, at \*4 (S.D.N.Y. Mar.12, 2004); *Nine West*, 80 F.Supp.2d at 192.

The Court agrees that, under certain circumstances, an antitrust conspiracy may depend on its own concealment to the point that any act in furtherance thereof can also be said to conceal it. As the Supreme Court explained long ago, the purpose of the fraudulent-concealment doctrine is to prevent a defendant from "concealing a fraud, or ... committing a fraud in a manner that it concealed itself until such time as the party committing the fraud could plead the statute of limitations to protect it." *Bailey v. Glover*, 88 U.S. (21 Wall.) 342, 349, 22 L.Ed. 636 (1874). However, the Court cannot find that conspiracies involving price-fixing are *per se* self-concealing, as such a finding would render them wholly exempt from the applicable statute of limitations.

\*22 Although not binding, *In re Publication Paper Antitrust Litig.*, No. 04–1631, 2005 WL 2175139 (D.Conn. Sept.7, 2005) provides a helpful framework under which to determine whether a conspiracy involving price-fixing is self-concealing for the purposes of establishing fraudulent concealment. That case found that a price-fixing conspiracy may be self-concealing, depending on the nature of the industry in which the item is price-fixed:

In a competitive, well-regulated industry it will often be the case that a price-fixing conspiracy, if not concealed, would immediately fail because of governmental or private legal action. In such circumstances, any announcement of a price increase will carry with it an implicit statement that the price increase is legitimate, i.e., the result of competitive forces, not collusion. Nevertheless, not every price-fixing conspiracy is self-concealing. For example, there may be industries in which the participants are aware of collusion but it is not stopped because of indifference, fear, or because the perpetrators are exempt from, or beyond the reach of, antitrust laws. In such circumstances, the defendants' announcement of a price increase will not carry with it any implied certification of legitimacy. and so, absent additional circumstances, will not be selfconcealing.

*In re Publication Paper*, 2005 WL 2175139, at \*4. Accordingly, "whether a particular price-fixing conspiracy or, more precisely, whether a particular announcement of a price increase necessarily conceals its true nature depends on the nature of the industry and the circumstances surrounding the

announcement." *Id.* In other words, a plaintiff must show circumstances indicating that a price increase "carries with it a pretense of legitimacy" or "that it would necessarily be assumed that [it was] the result of legitimate market forces." *Id.* To do so, a plaintiff may, for example, set forth allegations showing "that price increases are not abnormal, that such increases are typically ascribed to market forces, that an openly collusive price increase would not be tolerated, and that there was nothing suspicious about the circumstances under which each of the pre-limitations period price announcements were made." *Id.* 

Here, Plaintiffs fail to allege particular circumstances surrounding the MgO market indicating that the alleged conspiracy was self-concealing. Plaintiffs come close to pleading an affirmative act of concealment in alleging that "price increases for MgO were justified by references to tight supply, thinning margins, and increased energy and freight costs" (Direct CAC ¶ 51; Indirect CAC ¶ 58), however they fail to explain the particular circumstances surrounding Defendants' price increases and pretextual justifications for those increases—information which is in Plaintiffs' control in accordance with Rule 9(b). 20 Thus, Plaintiffs have failed to meet the first element of fraudulent concealment to toll the statute of limitations. However, the Court will grant Plaintiffs leave to amend to adequately plead either (1) circumstances surrounding the MgO market during the Class Period indicating that the alleged conspiracy is self-concealing, or (2) particular circumstances surrounding Defendants' price increases and the allegedly pretextual justifications for those price increases. See In re Burlington Coat Factory Litig., 114 F.3d at 1434.

Nor can Plaintiffs' conclusory allegation that "defendants met secretly and among themselves for the express purpose of fixing prices and allocating markets of domestically sold MgO" (Direct CAC ¶ 50; Indirect CAC ¶ 57) satisfy the affirmative act requirement.

# ii. Reliance

\*23 Defendants argue that Plaintiffs fail to meet the second element of fraudulent concealment because they have not alleged that that they relied on Defendants' alleged affirmative acts of concealment. Plaintiffs argue that there is no reliance requirement to establish fraudulent concealment.

While the aforementioned elements of fraudulent concealment do not specifically note a reliance requirement, the language of the second element strongly suggests one.

As previously noted, the second element of fraudulent concealment requires a showing that the defendant's concealment misled or relaxed the plaintiff's potential inquiry into what otherwise would have been evidence of its cause of action. In re Lower Lake Erie, 998 F.2d at 1179; see also Forbes v. Eagleson, 228 F.3d 471, 487 (3d Cir.2000) ("[T]he plaintiff must show that he actually was mis[led] ... into thinking that he d [id] not have a cause of action" (quotation and citation omitted)). Implicit in the notion that a plaintiff's inquiry was misled or relaxed by an act of concealment is that the plaintiff relied on that act of concealment. That is, the plaintiff's inquiry would not have been misled or relaxed if it did not rely on the defendant's act of concealment. Here, Plaintiffs make no allegations that they were misled by Defendants' concealment of the alleged conspiracy and therefore have failed to meet the second element of fraudulent concealment. However, the Court will grant Plaintiffs leave to amend to adequately plead that they relied on the selfconcealing nature of Defendants' conspiracy and/or pretextual justifications for Defendants' price increases. See In re Burlington Coat Factory Litig., 114 F.3d at 1434.

# iii. Due Diligence

Defendants argue that Plaintiffs fail to satisfy the due diligence element of fraudulent concealment because they do not allege any due diligence performed during the Class Period, particularly that which led to the discovery of the alleged conspiracy. Plaintiffs counter that, under the fraudulent concealment doctrine, they need only plead that they would not have discovered their claim, even in the exercise of reasonable due diligence. Plaintiffs further argue that determinations of due diligence are fact-intensive and therefore not properly addressed on a motion to dismiss.

The parties cite somewhat differently worded standards to support their respective positions on what the due diligence prong requires. Defendants cite *In re Lower Lake Erie*, in which the Court of Appeals held that a plaintiff must show that he "exercised due diligence in investigating his cause of action." 998 F.2d at 1178–79. Plaintiffs, on the other hand cite *Matthews v. Kidder, Peabody & Co., Inc.*, where the Court of Appeals held that a plaintiff must show that his ignorance is not attributable to a lack of "reasonable due diligence in attempting to uncover the relevant facts." 260 F.3d 239, 256 (3d Cir.2001).

While the wording of the due diligence prong has differed slightly among Third Circuit case law, its substance has remained consistent. The due diligence prong is rooted in

the notion of inquiry notice: that an injury accrues when a reasonable plaintiff under the circumstances would have discovered it. See Matthews, 260 F.3d at 251. As previously discussed, a federal antitrust injury accrues when an overt act is committed that injures the plaintiff, thereby triggering the four-year statute of limitations; however, one or more affirmative acts of concealment "may toll the statute of limitations [] if [they] mislead[] a plaintiff into thinking that he does not have a cause of action." Davis v. Grusemeyer, 996 F.2d 617, 624 (3d Cir.1993), overruled on other grounds by Rolo v. City Investing Co. Liquidating Trust, 155 F.3d 644 (3d Cir.1998). Thus, to establish the due diligence prong of fraudulent concealment, a plaintiff must affirmatively show that he was not on inquiry notice of the alleged antitrust conspiracy. See id. ("A key aspect of a plaintiff's case alleging fraudulent concealment is [ ] proof that the plaintiff was not previously on notice of the claim he now brings." (citations omitted)).

\*24 In this Circuit, "inquiry notice [is] analyzed in two steps." \*21 Matthews, 260 F.3d at 252. "First, the burden is on the defendant [s] to show the existence of 'storm warnings.' " Id. In this case, a storm warning would be information or data that would alert a reasonable MgO purchaser of ordinary intelligence to potentially culpable conduct. "Second, if the defendants establish the existence of storm warnings, the burden shifts to the plaintiffs to show that they exercised reasonable due diligence and yet were unable to discovery their injuries." Id. This requires Plaintiffs to show that (1) they investigated the storm warnings and (2) in their investigation, they exercised the due diligence expected of a reasonable DBM or CCM purchaser of ordinary intelligence. See id.

While the following inquiry notice analysis is laid out in the context of a RICO case, it has also been applied in antitrust cases involving price-fixing. See In re Aspartame Antitrust Litig., 416 Fed. App'x. 208, 211–12 (3d Cir.2011); In re Electrical Carbon Prods. Antitrust Litig., 333 F.Supp.2d 303, 317 (D.N.J.2004).

As Plaintiffs point out, this inquiry is necessarily bound up with the facts of the case because it "implicates factual questions as to when [a] plaintiff discovered or should have discovered the elements of the cause of action," *id.* at 250 (quotations and citation omitted); *see also Mercedez–Benz*, 157 F.Supp.2d at 373 ("At a minimum, this issue will involve assessing the factual circumstances surrounding the accused purchasing transactions and whether those circumstances would have put a reasonably diligent plaintiff on notice of a price-fixing conspiracy"), and, as a result, at the

pleading stage, this court has been hesitant to dismiss an otherwise fraudulently concealed antitrust claim for failure to sufficiently allege due diligence. *See In re Electrical Carbon Prods.*, 333 F.Supp.2d at 317–18; *Mercedez–Benz*, 157 F.Supp.2d at 374.

Citing to *In re Publication Paper* and *Hinds County*, Defendants maintain that, at the pleading stage, the due diligence prong nonetheless requires that "Plaintiffs [ ] allege with particularity when the Named Plaintiffs or Class members became aware of the antitrust violations and what inquiries [they] made into the activities alleged in the complaint." (Sumitomo Reply Br., 18) (internal quotations omitted). In *In re Publication Paper*, the plaintiffs alleged that they were aware of certain suspicious activities two years before the end of the limitations period. *See* 2005 WL 2175139, at \*5. Accordingly, the court found that the plaintiffs were therefore required allege they steps they took to investigate those activities. *See id.* Here, however, Plaintiffs do not allege any suspicious activities or storm warnings within the limitations period.

Defendants' citation to *Hinds County* is more persuasive. In that case, the plaintiffs attempted to satisfy the due diligence prong by alleging that they "did not discover, nor could have discovered through reasonable diligence, that [d]efendants and their co-conspirators were violating the antitrust laws until shortly before this litigation was commenced, because [d]efendants and their co-conspirators were using deceptive and secret methods to avoid detection and affirmatively conceal their violations." *Hinds County*, 620 F.Supp.2d at 521–22. The court found that allegation too vague to satisfy Rule 9(b) and further explained that to deem such an allegation sufficient would "allow[] the allegations required to satisfy the first prong of fraudulent concealment to also satisfy the third prong." *Id.* at 521–22.

\*25 The Court finds this logic persuasive. Here, Plaintiffs allege that, due to the secretive nature of the alleged MgO conspiracy, "neither plaintiffs nor the class members had knowledge of any of the foregoing violations, and neither plaintiffs nor the class members, until recently, could have discovered through reasonable diligence that [D]efendants and their co-conspirators had engaged in the foregoing violations." (Direct CAC ¶ 49; Indirect CAC ¶ 56 .) This allegation cannot satisfy the requirements of Rule 9(b), particularly when it fails to encompass when and how Plaintiffs ultimately discovered the alleged MgO conspiracy—information that is certainly with Plaintiffs' control. See

In re Craftmatic, 890 F.2d at 645. Without some level of specificity regarding Plaintiffs' discovery of the alleged conspiracy, it is impossible to discern whether Plaintiffs could or should have discovered it within the limitations period. Thus, Plaintiffs have failed to meet the due diligence prong of fraudulent concealment. However, Plaintiffs will be granted leave to amend to adequately plead, in accordance with Rule 9(b), (1) when and how they discovered the alleged MgO conspiracy, and (2) that the self-concealing nature of the conspiracy and/or pretextual justifications for Defendants' price increases made it so that they were not alerted to any storm warnings that would otherwise trigger an obligation to perform due diligence. See In re Burlington Coat Factory Litig., 114 F.3d at 1434.

# E. IP Plaintiffs' Claims for Violations of Various States' Consumer Protection Laws

IP Plaintiffs assert claims under California, Florida, Hawaii, Massachusetts, Montana, Nebraska, New Hampshire, New York, South Carolina, and Vermont consumer protection and unfair competition laws. As with IP Plaintiffs' antitrust claims under state law, Defendants argue that IP Plaintiffs lack standing to assert their consumer protection claims, except that under California law, because they "do not allege purchases in any of the 10 states other than California." (Sumitomo (IP Pl.'s) Br., 5). Defendants further argue that these claims should be dismissed because IP Plaintiffs do not plead them with particularity in accordance with Federal Rule of Civil Procedure 9(b).

#### i. Standing

IP Plaintiffs' standing to sue under a state's consumer protection law is analogous to their standing under a state's antitrust law. As discussed in Point B, IP Plaintiffs' failure to tie their injuries or Defendants' unlawful conduct to a number of states was fatal to their standing to sue because the antitrust laws of those states require a showing that part of Defendants' conduct occurred or had an effect in-state. On the other hand, IP Plaintiffs have standing to sue under the antitrust laws that have no such requirement.

Similarly, many of the consumer protection and unfair competition laws asserted by IP Plaintiffs require that Defendants' unlawful conduct affect trade and commerce in the state under whose law they are suing, see MCA 30–14–103, 102 (Montana) ("Unfair methods of competition and unfair or deceptive acts or practices in the conduct of any trade or commerce are unlawful.... [T]rade or commerce [must]

directly or indirectly affect[ ] the people of this state."); MGLA §§ 93A 1, 2 (Massachusetts) (same); S.C.Code 1976 §§ 39-5-10, 20 (South Carolina) (same); Neb. Rev. St. §§ 59–1602, 1601 (Nebraska) ("Unfair methods of competition and unfair or deceptive acts or practices in the conduct of any trade or commerce shall be unlawful.... Trade and commerce shall mean the sale of assets or services and any commerce directly or indirectly affecting the people of the State of Nebraska."); N.H.Rev.Stat. § 358-A:2 (New Hampshire) ("It shall be unlawful for any person to use any unfair method of competition or any unfair or deceptive act or practice in the conduct of any trade or commerce within this state."); N.Y. Gen. Bus. Law § 349 (New York) ("Deceptive acts or practices in the conduct of any business, trade or commerce or in the furnishing of any service in this state are hereby declared unlawful."); Sherman v. Ben & Jerry's Franchising, Inc., 08-CV-207, 2009 WL 2462539, at \*10 (D.Vt. Aug. 10, 2009) (Out of state plaintiffs alleging out of state conduct do not have standing to sue under Vermont Consumer Fraud Protection Act), while others do not, see F.S.A. 501.204, 501.211 (Florida); HRS 480–2, 480–13 (Hawaii).<sup>22</sup>

22 Thus, contrary to Defendants' contention, the fact that IP Plaintiffs fail to allege that they reside or purchased an MgO product in a given state does not automatically deprive them of standing to sue under the state's consumer protection or unfair competition law. To be sure, the case Defendants cite in support of this contention held that the named plaintiffs in that case lacked standing to assert consumer protection and unfair competition claims under the laws of states in which they neither resided nor suffered an injury. See In re Potash 667 F.Supp.2d at 924. However, the Court cannot accept this holding as a bright line rule. Standing issues are intimately bound up with the elements of the particular claim asserted, as a plaintiff must establish that his injury is "fairly traceable to the challenged action of the defendant." Lujan, 504 U.S. at 560; see also Blum, 457 U.S. at 999 ("The complaining party must also show that he is within the class of persons who will be concretely affected."); Allen, 468 U.S. at 752 ("[T]he standing inquiry requires careful judicial examination of a complaint's allegations to ascertain whether the particular plaintiff is entitled to an adjudication of the particular claims asserted.").

\*26 IP Plaintiffs' allegations that "Defendants agreed to, and did in fact, act in restraint of trade or commerce in a market that includes the above states, by affecting, fixing, controlling, and/or maintaining, at artificial and noncompetitive levels, the prices at which MgO and MgO

Products were sold, distributed, or obtained in those states;" "MgO price competition was restrained, suppressed, and eliminated throughout the states;" and "MgO prices were raised, fixed, maintained, and stabilized at artificially high levels throughout the states" (Indirect CAC ¶¶ 79, 81) are conclusory and do not tie their injuries to the alleged conspiracy's effect on trade and commerce in those specific states. Therefore, IP Plaintiffs' consumer protection claims under Montana, Massachusetts, Nebraska, New Hampshire, and New York law are dismissed for lack of standing.

### ii. Pleading Requirements

The consumer protection laws of Florida and Hawaii—under which IP Plaintiffs currently maintain standing to suerequire that they plead the circumstances of any alleged fraudulent conduct with particularity in accordance with Rule 9(b). See Jovine v. Abbott Laboratories, Inc., 11–CV–80111, 2011 WL 1376029 (S.D.Fla. Apr. 12, 2011) (applying Rule 9(b) to allegations of unfair or deceptive acts or practices under the Florida Deceptive and Unfair Trade Practices Act); Cannon v. U.S. Bank, NA, Civ. No. 11-00079, 2011 WL 1637415, (D.Hawai'i Apr.29, 2011) (applying Rule 9(b) to allegations of fraudulent business practices under the Hawaii State Unfair and Deceptive Business Practices Act); Athena Feminine Techs., Inc. v. Wilkes, No. C 10-4868, 2011 WL 4079927 (N.D.Cal. Sept.13, 2011) ("[A] claim brought under the fraudulent prong of the [Unfair Competition Law] must be pled with particularity under Rule 9(b)").

IP Plaintiffs' allegations that "Defendants deliberately failed to disclose material facts to Plaintiff and the classes concerning Defendants' unlawful activities and artificially inflated prices for MgO and MgO Products," and "misrepresented to all consumers during the Class Period that Defendants' MgO prices were competitive and fair" (Indirect CAC ¶ 80); see also (Indirect CAC ¶ 83) (alleging "affirmative misrepresentations and omissions concerning the price of MgO") are not set forth with any measure of particularity. See In re Supreme Specialties, Inc. Sec. Litig., 438 F.3d 256, 270 (3d Cir.2006) (Under Rule 9(b), a plaintiff must allege fraud with particularity by pleading the following: "(1) a specific false representation [or omission] of material fact; (2) knowledge by the person who made it of its falsity; (3) ignorance of its falsity by the person to whom it was made; (4) the intention that it should be acted upon; and (5) that the plaintiff acted upon it to his [or her] damage." (quotations and citation omitted)). Accordingly, IP Plaintiffs' consumer protection and unfair competition claims under Florida and Hawaii law are dismissed to the extent they are premised on Defendants' fraudulent conduct. However, IP Plaintiffs are granted leave to amend their allegations to comply with the requirements of Rule 9(b). Additionally, at this time, those claims may move forward to the extent they are premised on allegations of Defendants' engaging in unfair competition, as there is no indication that Rule 9(b) applies to such allegations.

#### III. CONCLUSION

- \*27 For the foregoing reasons, Defendants' Motion to Dismiss is GRANTED to the following extent only. The Court rules as follows:
  - (1) IP Plaintiffs' federal and state antitrust claims are dismissed without prejudice for lack of standing. IP Plaintiffs have thirty (30) days to amend their allegations to set forth (1) the specific products purchased containing DBM or CCM and (2) the nexus between an increase in the price of those products and the alleged conspiracy to fix prices in and allocate shares of the domestic DBM and CCM markets.
  - (2) IP Plaintiffs' antitrust claims under Arizona, the District of Columbia, Hawaii, Illinois, Maine, Minnesota, Nebraska, Nevada, New Mexico, New York, North Carolina, North Dakota, Oregon, South Dakota, Tennessee, Utah, and West Virginia law are dismissed with prejudice for lack of standing.
  - (3) Plaintiffs' federal and state antitrust claims are dismissed without prejudice as time-barred under the applicable statutes of limitations. Plaintiffs have thirty (30) days to amend their allegations of fraudulent concealment to equitably toll those statutes of limitations.
  - (4) IP Plaintiffs' consumer protection and unfair competition claims under Montana, Massachusetts, Nebraska, New Hampshire, and New York are dismissed with prejudice for lack of standing.
  - (5) IP Plaintiffs' consumer protection and unfair competition claims under Florida and Hawaii law are dismissed without prejudice to the extent they are premised on allegations of Defendants' fraudulent conduct. IP Plaintiffs have thirty (30) days to amend those allegations to comply with Federal Rule of Civil Procedure 9(b).

Case 1:19-md-02875-RMB-SAK Document 1451-1 Filed 08/02/21 Page 199 of 322 In re Magnesium Oxide Antitrust Litigation, Not Reported in Fastion 2011)

2011 WL 5008090, 2012-1 Trade Cases P 77,878

The Court will enter an order implementing this opinion.

# **All Citations**

Not Reported in F.Supp.2d, 2011 WL 5008090, 2012-1 Trade Cases P 77,878

**End of Document** 

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# Tab 23

# UNITED STATES DISTRICT COURT DISTRICT OF NEW JERSEY

# IN RE METFORMIN MARKETING AND SALES PRACTICES LITIGATION

Civil Action No. 20-2324

**ORDER** 

**THIS MATTER** comes before the Court on the Manufacturer Defendants' and Pharmacy Defendants' Motions to Dismiss pursuant to Federal Rules of Civil Procedure 12(b)(1) and 12(b)(6), ECF Nos. 78 & 80;

and it appearing that Plaintiffs<sup>2</sup> oppose the Motions, ECF No. 95;

and it appearing that this putative class action arises out of the allegedly adulterated, misbranded, and/or unapproved manufacturing, sale, and distribution of metformin-containing drugs ("MCDs") by Defendants, see generally Am. Compl., ECF No. 58;

and it appearing that Metformin is the leading drug used in the treatment and management of type 2 diabetes and is the fourth most prescribed drug in the United States, id. ¶¶ 2, 4;

<sup>&</sup>lt;sup>1</sup> This consolidated putative class action is brought against two groups of Defendants: manufacturers and pharmacies. First, Plaintiffs bring this action against sixteen manufacturers (the "Manufacturer Defendants"). Of those sixteen, eleven joined the Manufacturer Defendants' Motion: Actavis, LLC, Actavis Pharma, Inc., Amneal Pharmaceuticals LLC, Ascend Laboratories, LLC, Aurobindo Pharma USA, Inc., Aurolife Pharma, LLC, Granules Pharmaceuticals, Inc., Granules USA, Inc. Heritage Pharmaceuticals, Inc d/b/a Avent Pharmaceuticals Inc., and Teva Pharmaceuticals USA Inc. See ECF No. 78. Amneal Pharmaceuticals Inc. and AvKARE Inc. have since joined the Motion. ECF No. 87. Second, Plaintiffs bring this action against four named pharmacies (the "Pharmacy Defendants"), three of which have joined the Pharmacy Defendants' motion to dismiss: CVS Pharmacies, Inc. (plead as CVS Health Corporation), Walgreens Boot Alliance, Inc., and Rite-Aid Corporation. See ECF No. 80, 89, 103. Although not a Pharmacy Defendant, AvKARE Inc. similarly joins the Pharmacy Defendants' Motion in part.

<sup>&</sup>lt;sup>2</sup> There are eight proposed Class Representative Plaintiffs in the instant action. First, seven Plaintiffs seek to represent the interests of consumers who purchased Defendants' MCDs (the "Consumer Plaintiffs"): Joseph Brzozowski and Jacqueline Harris (citizens and residents of New Jersey), Michael Hann, Mohammad Rahman, and Elaine Wohlmuth (citizens and residents of California), Stelios Mantalis (citizen and resident of New York), and Kristin Wineinger (citizen and resident of Indiana). Second, one Plaintiff, MSP Recover Claims, Series LLC ("MSPRC"), seeks to represent the interests of third-party payors ("TPPs") who made co-payments for Defendants' MCDs.

and it appearing that the Manufacturer Defendants allegedly manufactured—or are closely affiliated with entities that manufactured—MCDs that were contaminated with a probable human carcinogen known as N-nitrosodimethylamine ("NDMA"), id. ¶¶ 6, 28;

and it appearing that Plaintiffs bring this action on behalf of millions of MCD consumers as well as third-party payors ("TPPs") who bought or made reimbursements for the Manufacturer Defendants' MCDs that were rendered worthless as a result of the NDMA contamination, id. ¶ 6; and it appearing that the Consumer Plaintiffs each allege that they "paid money for one or more of Defendants' MCDs," and that despite it being warranted that the MCDs were the same as the brand drug (known as the "reference listed drug" or "RLD"), they received "a product that was not the same" as the RLD, id. ¶¶ 12-18;

and it appearing that MSPRC alleges that it was assigned the rights and claims to recovery of TPPs who made payments for Defendants' allegedly adulterated drugs, id. ¶¶ 19-27;

and it appearing that Plaintiffs further contend that they sustained economic damages because they "paid for or made reimbursements for generic MCDs that were illegally and willfully introduced into the market by Defendants," id. ¶ 11;

and it appearing that Defendants now move to dismiss Plaintiffs' Amended Complaint, arguing, among other things, that Plaintiffs lack standing, ECF Nos. 78 & 80;<sup>3</sup>

<sup>&</sup>lt;sup>3</sup> A motion to dismiss for lack of standing is properly brought pursuant to Rule 12(b)(1). See Bellentine v. United States, 486 F.3d 806, 810 (3d Cir. 2007). Under Rule 12(b)(1), a plaintiff bears the burden of persuading the Court that subject matter jurisdiction exists. See Kehr Packages, Inc. v. Fidelcor, Inc., 926 F.2d 1406, 1409 (3d Cir. 1991). In resolving a Rule 12(b)(1) motion, a court first determines whether the motion presents a "facial" or "factual" attack. See Constitution Party of Pa. v. Aichele, 757 F.3d 347, 357 (3d Cir. 2014). A facial attack argues that a claim on its face "is insufficient to invoke the subject matter jurisdiction of the court," id. at 358, and "does not dispute the facts alleged in the complaint," Davis v. Wells Fargo, 824 F.3d 333, 346 (3d Cir. 2016). A court reviewing a facial attack must "consider the allegations of the complaint and documents referenced therein and attached thereto, in the light most favorable to the plaintiff." Constitution Party of Pa., 757 F.3d at 358. Here, Defendants' motions to dismiss for lack of standing present facial attacks because they challenge Plaintiffs' standing to bring this lawsuit according to the pleaded facts. See Mfr. Def. Mem. at 13-20, ECF No. 78.1; Pharmacy Def. Mem. at 12-15, ECF No. 80.1. The Court thus accepts the pleaded facts as they relate to Plaintiffs' standing as true and draws all reasonable inferences in Plaintiffs' favor. See Constitution Party of Pa., 757 F.3d at 358.

and it appearing that a litigant seeking to invoke federal jurisdiction must establish that they have standing to sue, <u>Lujan v. Defs. of Wildlife</u>, 504 U.S. 555, 561 (1992);

and it appearing that a plaintiff has standing if they have "(1) suffered an injury in fact, (2) that is fairly traceable to the challenged conduct of the defendant, and (3) that is likely to be redressed by a favorable decision," Spokeo, Inc. v. Robins, 136 S. Ct. 1540, 1547 (2016) (citing Lujan, 504 U.S. at 560-61);

and it appearing that Plaintiffs lack standing for two reasons;

and it appearing that first, the Consumer Plaintiffs have failed to demonstrate that they suffered an injury as they have not alleged that they purchased or ingested any MCDs containing NDMA;

and it appearing that although each Consumer Plaintiff alleges that they bought a product that was not the same as the RDL and that was "illegally and willfully introduced into the market by Defendants," Am. Compl. ¶¶ 11-18, they do not allege that they purchased NDMA-contaminated MCDs from Defendants;<sup>4</sup>

and it appearing that instead the Consumer Plaintiffs seek to bring this action "on behalf of" the consumers who paid for "Defendants' MCDs [that] were adulterated and/or misbranded . . . through contamination with [NDMA]," id. ¶ 6;

and it appearing, however, that a class representative must show that they themselves suffered an injury and cannot merely rely upon the standing of individuals in the proposed class, see Spokeo, 136 S. Ct. at 1547 n.6 (2016) (explaining that class action suits maintain the same injury-in-fact requirement as every other case: each class representative "must allege and show

<sup>&</sup>lt;sup>4</sup> In contrast, MSPRC has adequately alleged that it suffered an injury, as it contends that it was assigned the rights of certain TPPs who made payments for the Manufacturer Defendants' MCDs contaminated with NDMA. Am. Compl. ¶ 27. In support, MSPRC provides examples of the payments that were made by its assignors. See id.

that they personally have been injured, not that injury has been suffered by other unidentified members of the class to which they belong") (internal quotation marks and citations omitted);

and it appearing that the Consumer Plaintiffs have thus failed to allege that they suffered an injury;<sup>5</sup>

and it appearing that second, Plaintiffs have not shown causation because they have failed to connect each Defendants' actions to at least one injured Plaintiff, see Cent. States Se. & Sw. Area Health & Welfare Fund v. Merck-Medco Managed Care, LLC, 504 F.3d 229, 241 (2d Cir. 2015) ("To establish Article III standing in a class action, it is not required that each named plaintiff must have a claim against each named defendant. Rather, for every named defendant there must be at least one named plaintiff who can assert a claim directly against that defendant. . . . ") (quoting 1 Newberg on Class Actions § 2:6 n.3 (4th ed. 2002));

and it appearing that no Consumer Plaintiff alleges (1) which Manufacturer Defendant's drug they purchased, or (2) at which Pharmacy Defendant they purchased their drugs, so the Court, therefore, cannot link each Defendant to any injury suffered by any Consumer Plaintiff;

and it appearing that although MSPRC alleges that the TPPs who assigned their rights to MSPRC made payments for the Manufacturer Defendants' adulterated drugs, they too do not allege any involvement by the Pharmacy Defendants;

and it appearing that Plaintiffs have thus failed to show causation;6

<sup>&</sup>lt;sup>5</sup> The Consumer Plaintiffs contend that they plausibly allege that they bought an MCD contaminated with NDMA. The Court disagrees. A complaint must "state, clearly and concisely, the injury suffered by <u>each</u> Plaintiff as a result of the alleged wrongs committed by defendants." <u>El Ameen Bey v. Stumpf</u>, 825 F. Supp. 2d 537, 560 (D.N.J. 2011). By failing to allege that they bought one of Defendants' MCDs contaminated with NDMA, Plaintiffs have not adequately alleged any injury suffered.

<sup>&</sup>lt;sup>6</sup> Plaintiffs argue that they may plead different defendants caused harm "in the alternative" under Federal Rule of Civil Procedure 8(d). But Plaintiffs do not plead "in the alternative;" rather, Plaintiffs fail to allege that <u>any</u> Defendant caused them harm. Plaintiffs also cite to <u>In re Asacol Antitrust Litig.</u>, 907 F.3d 42 (1st Cir. 2018), for the proposition that named plaintiffs in a class action have standing to assert claims on behalf of absent class members in other states. This is true, but the named plaintiffs still must establish their own standing as a threshold matter. Finally, the majority of Plaintiffs' opposition focuses on the fact that a plaintiff need not prove direct, proximate harm to establish

IT IS on this 20th day of May, 2021;

**ORDERED** that Defendants' Motions to Dismiss for lack of standing, ECF Nos. 78 & 80, are **GRANTED**; and it further

**ORDERED** that to the extent Plaintiffs can cure the deficiencies identified in this order, they may file amended pleadings within thirty (30) days.

/s Madeline Cox Arleo
HON. MADELINE COX ARLEO
UNITED STATES DISTRICT JUDGE

traceability, but rather can rely upon indirect harm. Again, this is beside the point. Plaintiffs here do not allege facts suggesting that any of the Defendants caused, directly or indirectly, their alleged injury.

# Tab 24

1

Case 1:19-md-02875-RMB-SAK Document 1451 Milman v. FCA U.S., LLC, Not Reported in Fed. Supp. (2018). Page 10:3326

2018 WL 5867481

2018 WL 5867481 Only the Westlaw citation is currently available. United States District Court, C.D. California.

> Brenna MILMAN et al. v. FCA U.S., LLC, et al.

Case No. SACV 18-00686 JVS(SSx) | | Filed 08/30/2018

**Attorneys and Law Firms** 

Proceedings: (IN CHAMBERS) Order Granting Defendant's Motion to Dismiss Class Action Complaint

James V. Selna, Judge

\*1 The Court, having been informed by the parties in this action that they submit on the Court's tentative ruling previously issued, hereby GRANTS the Defendants' Motion to Dismiss Class Action Complaint and rules in accordance with the tentative ruling as follows:

On July 17, 2018, Defendant FCA U.S., LLC ("FCA") filed this motion to dismiss or, in the alternative, motion to strike the Class Action Complaint ("Complaint"). Mot., Docket No. 21. Plaintiff Brenna Milman ("Milman") opposed. Opp'n, Docket No. 27. FCA replied. Reply, Docket No. 30.

For the following reasons, the Court **grants** the motion to dismiss. The motion to strike is therefore moot.

### I. Background

# A. Requests for Judicial Notice

FCA filed a request for judicial notice ("RJN") in support of its motion to dismiss. Defendant's RJN, Docket No. 21-1. Milman also filed a request for judicial notice in support of her opposition to the motion. Plaintiff's RJN, Docket No. 27-1. Neither party opposed the other's request.

Defendant asks the Court to take judicial notice of (1) the order of dismissal in Preston v. Am. Honda Motor Co., No. 2:18-cv-00038, ECF #77, 2018 WL 5099507 (C.D. Cal. May 24, 2018); (2) the Third Amended Complaint in Heber v. Toyota Motor Sales U.S.A., Inc., No. SACV 16–01525 AG (JCGx), 2018 WL 3104612 (C.D. Cal. Jun. 11, 2018); and (3) Milman's October 6, 2017 letter to FCA requesting reimbursement. Milman asks the Court to take judicial notice of the time schedule order for both Heber and Preston in their appeals to the Ninth Circuit.

Under Federal Rule of Evidence 201, the Court may take judicial notice of "a fact that is not subject to reasonable dispute" if it is "generally known" in the jurisdiction or it "can be accurately and readily determined from sources whose accuracy cannot reasonably be questioned." Fed. R. Evid. 201(b). Because factual challenges have no bearing under Rule 12(b)(6), generally, the Court may not consider material beyond the pleadings in ruling on a motion to dismiss. Lee v. City of L.A., 250 F.3d 668, 688 (9th Cir. 2001), overruled on other grounds, Galbraith v. Ctv. of Santa Clara, 307 F.3d 1119, 1125 (9th Cir. 2002). However, there are several exceptions to this rule that do not demand converting the motion to dismiss into one for summary judgment. Id. at 688. The Court may take judicial notice of material submitted as part of the complaint or, if not physically attached to the complaint, material if its authenticity is not contested and it is necessarily relied upon by the complaint. Id.; United States v. Corinthian Colleges, 655 F.3d 984, 998-99 (9th Cir. 2011); Knievel v. ESPN, 393 F.3d 1068, 1076 (9th Cir. 2005). Additionally, judicial notice is appropriate for court filings and other matters of public record. Reyn's Pasta Bella, LLC v. Visa USA, Inc., 442 F.3d 741, 746 n.6 (9th Cir. 2006); U.S. ex rel. Robinson Rancheria Citizens Council v. Borneo, Inc., 971 F.2d 244, 248 (9th Cir. 1992).

\*2 Judicial notice of the documents requested by both parties is appropriate because all of the documents are either court filings, or their authenticity is uncontested and they are necessarily relied on in the Complaint. Defendant's RJN, Docket No. 21-1; Plaintiff's RJN, Docket No. 27-1. Therefore, the Court takes judicial notice of the documents.

#### **B. Factual Background**

FCA designs, manufactures, markets, distributes, and sells Jeep automobiles throughout the United States. Compl., Docket No. 1 ¶ 24. In 2017, Milman purchased a 2017 Jeep Wrangler from Champion Dodge, an authorized FCA dealer located in Downey, California. <u>Id.</u> ¶ 15. In or about September 19, 2017, Milman brought her vehicle in for a

service appointment at a Courtesy Chrysler Dodge in San Juan Capistrano, California after she noticed that her vehicle "was not operating properly." Id. ¶ 17. It was then discovered that her vehicle was not operating properly because rodents had entered the engine compartment and chewed up wiring which used soy-based materials. Id. The total cost to Milman for the repair was \$437.50. Id. On September 26, 2017, Milman sent a letter seeking reimbursement to both the dealership where she purchased the vehicle and the dealership where it was repaired. Id. On October 6, 2017, Milman also wrote a letter to FCA's Customer Care Department in Michigan to set up a claim, but has received no response to any of her correspondence. Id. ¶ 18.

Over the past decade, FCA and other automobile manufacturers have migrated from petroleum-based wiring insulation to plant, soy, or other bio-based insulation because it is less expensive and more environmentally friendly. Id. ¶ 31. Because rodents are attracted to such materials, the use of soy- or bio-based materials is alleged to have "created a bed and breakfast for rodents and other animals and pests" at the expense of vehicle owners and lessees. Id. ¶ 34. The use of these materials is thus not suitable for its intended protective purpose because it "compromis[es] the integrity" of the vehicles' electrical systems, rendering the vehicles "fully or partially inoperable." Id. ¶¶ 35-36. The Complaint alleges that this renders the use of soy- or bio-based materials defective. Id. ¶ 2.

The Complaint alleges that FCA was or should have been aware of the alleged defect through "(1) its own records of customers' complaints; (2) dealership repair records; (3) [National Highway Traffic Safety Administration ("NHTSA") | records; (4) warranty and post-warranty claims; (5) internal durability testing; and (6) other various sources." Id. ¶ 39. The issue is also alleged to have been "widely publicized and known within the automotive industry," as "a number of ... consumer interest stories" have been done on the issue by news stations across the U.S. Id. ¶¶ 41-42. Further, employees at Jeep dealerships "routinely inform consumers that rodent-based damage is very common, and have even acknowledged that it is the bio-based or soybased materials ... that are attracting these pests." Id. ¶ 49. The Complaint also points to three internet comments by Class Vehicle owners describing rodent-based damage that they have experienced, as well as complaints on the NHTSA website, to show that Milman's experience in the instant action is not isolated. Id. ¶¶ 50-52.

The Complaint also alleges that FCA should have known about the alleged defect because its agents and dealers "routinely" refuse to provide warranty coverage for rodent damage. Id. ¶ 40. The written Basic Warranty (the "Warranty") at issue provides, in relevant part, that the customer will not be liable for costs associated with defects in "material, workmanship, or factory preparation." Id. ¶ 53. The Warranty also includes exceptions for "tires" and "environmental factors." Id. ¶¶ 53, 55.

\*3 On April 23, 2018, Milman filed this putative class action on behalf of herself and all others similarly situated against FCA for its alleged use of soy- and bio-based materials in its vehicles' electrical wiring systems and other components (the "Class Vehicles"). Id. ¶ 2. The claims focus both on allegations that FCA knew of the alleged defect and concealed it from consumers, and that FCA refuses to provide Warranty coverage for damage resulting from the alleged defect. See <u>id.</u> ¶¶ 1-13.

The Complaint asserts eleven causes of action: (1) violation of the Magnuson-Moss Warranty Act, 15 U.S.C. § 2301 et seq.; (2) breach of express warranty; (3) breach of the implied warranty of merchantability; (4) declaratory relief; (5) violations of California's Unfair Competition Law ("UCL"), Cal. Bus. & Prof. Code §§ 17200 et seq.; (6) violation of the Consumer Legal Remedies Act ("CLRA"), Cal. Civ. Code §§ 1750 et seq.; (7) violation of the Song-Beverly Consumer Warranty Act, Cal. Civ. Code §§ 1791.2 and 1793.2; (8) violation of the Song-Beverly Consumer Warranty Act, Cal. Civ. Code §§ 1791.1 and 1792; (9) breach of express warranty; (10) breach of implied warranty; and (11) fraud/ fraudulent concealment. 2 Id. ¶¶ 74-237.

2 Milman pleads duplicative claims for breach of express warranty (counts II and IX) and implied warranty (counts III and X).

FCA now moves to dismiss to dismiss the Complaint in its entirety and to strike certain allegations. Mot., Docket No. 21.

# **II. Motion To Dismiss**

#### A. Legal Standards

1. Federal Rule of Civil Procedure 12(b)(6)

Under Federal Rule of Civil Procedure 12(b)(6), a defendant may move to dismiss for failure to state a claim upon which relief can be granted. A plaintiff must state "enough facts

to state a claim to relief that is plausible on its face." <u>Bell Atl. Corp. v. Twombly</u>, 550 U.S. 544, 570, 127 S.Ct. 1955, 167 L.Ed.2d 929 (2007). A claim has "facial plausibility" if the plaintiff pleads facts that "allow[] the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." <u>Ashcroft v. Iqbal</u>, 556 U.S. 662, 663, 129 S.Ct. 1937, 173 L.Ed.2d 868 (2009).

In resolving a 12(b)(6) motion under Twombly, a court must follow a two-step approach. Id. at 679, 129 S.Ct. 1937. First, a court must accept all well-pleaded factual allegations as true, but "[t]hread-bare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice." Id. at 677, 129 S.Ct. 1937. Furthermore, a court must not "accept as true a legal conclusion couched as a factual allegation." Id. at 677–78, 129 S.Ct. 1937 (quoting Twombly, 550 U.S. at 555, 127 S.Ct. 1955). Second, assuming the veracity of wellpleaded factual allegations, a court must "determine whether they plausibly give rise to an entitlement to relief." Id. at 664, 129 S.Ct. 1937. This determination is context-specific, requiring a court to draw on its experience and common sense, but there is no plausibility "where the well-pleaded facts do not permit the court to infer more than the mere possibility of misconduct." Id.

## 2. Federal Rule of Civil Procedure 9(b)

Under Federal Rule of Civil Procedure 9(b), a plaintiff must plead each element of a fraud claim with particularity, i.e., the plaintiff "must set forth more than the neutral facts necessary to identify the transaction." Cooper v. Pickett, 137 F.3d 616, 625 (9th Cir. 1997) (emphasis in original) (quoting In re GlenFed, Inc. Sec. Litig., 42 F.3d 1541, 1548 (9th Cir. 1994)). A fraud claim must be accompanied by "the who, what, when, where, and how" of the fraudulent conduct charged. Vess v. Ciba-Geigy Corp. USA, 317 F.3d 1097, 1106 (9th Cir. 2003) (quoting Cooper, 137 F.3d at 627). "A pleading is sufficient under rule 9(b) if it identifies the circumstances constituting fraud so that a defendant can prepare an adequate answer from the allegations." Moore v. Kayport Package Express, Inc., 885 F.2d 531, 540 (9th Cir. 1989). Statements of the time, place, and nature of the alleged fraudulent activities are sufficient, but mere conclusory allegations of fraud are not. Id.

#### **B.** Discussion

- 1. Plausible Theory of Liability
- \*4 FCA argues that the Complaint fails the basic pleading standards of Rule 8(a) because (1) the events giving rise

to the claims are as consistent, if not more consistent, with an "innocuous alternative explanation" as with the alleged defect; and (2) Milman fails to specify which component(s) are purportedly defective in her own vehicle and pleads no facts to support her defect theory. Mot., Docket No. 21 at 4-8; Reply, Docket No. 30 at 1-4. Milman argues in opposition that (1) there is no innocuous alternative explanation for the facts giving rise to her claims; and (2) she has pled the defect with enough specificity to survive dismissal. Opp'n, Docket No. 27 at 4-7.

FCA argues that it is equally plausible that rodents chewed on the wires in Milman's vehicle simply because they are wires, and would have done so regardless of the materials used, as it is that they chewed on the wires because they are "soy-based." Mot., Docket No. 21 at 5.<sup>3</sup> Milman argues in opposition that there can be no "innocuous alternative explanation" because she has pled with specificity that the soy- or bio-based wiring "attracted the rodents to feast" on the wires, resulting in the vehicles becoming inoperable. Opp'n, Docket No. 27 at 4-5.

FCA references various blogs and websites in support of this argument. See Mot., Docket No. 21 at 5. However, the Court generally may not consider any material beyond the pleadings in ruling on a motion to dismiss.

Lee, 250 F.3d at 668. Thus, the Court does not consider these references in its analysis.

A complaint pleading facts which are "merely consistent with" a defendant's liability "stops short of the line between possibility and plausibility of entitlement to relief." Iqbal, 556 U.S. at 678, 129 S.Ct. 1937. Rather, a plausible claim requires that plaintiffs plead facts that "tend to exclude a plausible and innocuous alternative explanation." See Eclectic Props. East, LLC v. Marcus & Millichap Co., 751 F.3d 990, 998 (9th Cir. 2014).

The Complaint alleges that rodents are "uniquely attracted" to soy- and bio-based materials. Compl., Docket No. 1 ¶ 4; see also id. ¶¶ 34; 35; 42; 43; 49. It also alleges that "a number of news stations ... have done consumer interest stories" on the issue, with one stating "apparently, rodents love to gnaw on [soy-based coating]." Id. ¶ 42. It is further alleged that "older vehicles manufactured without [soy-based] materials that are exposed to similar conditions do not experience rodent and wild animal caused damage." Id. ¶ 47. The Complaint also alleges that employees at FCA dealerships "routinely inform consumers that rodent damage is very common, and have even acknowledged that it is the bio-based or soy-based materials in the automobiles that are attracting

these pests." <u>Id.</u> ¶ 49. Finally, the Complaint alleges three internet comments from others who have described similar experiences with their own Class Vehicles. <u>Id.</u> ¶ 51.

The Court agrees with Milman that the facts alleged tend to exclude an alternative explanation. Milman bases her theory on her own experiences, news reports, statements from dealership employees, and consumer complaints. FCA's "innocuous" explanation that rodents have a natural propensity to chew on things is not enough to dismiss Milman's claims. FCA's call for Milman to quantify how much more likely rats are to chew on soy-coated wires than other types of wires asks too much at this stage in the proceedings. See Mot., Docket No. 21 at 6.

FCA also argues that the Complaint is deficient because Milman does not identify "what specific component(s) are purportedly 'defective' in her own vehicle." Mot., Docket No. 21 at 6; Reply, Docket No. 30 at 3-4. Milman argues in opposition that she has pled the defective components with the requisite level of specificity because the Complaint puts only the soy-based wires at issue, rather than all the wires in the vehicle. Opp'n, Docket No. 27 at 7.

\*5 The Court agrees with Milman that the Complaint need not identify the precise wire at issue to survive a motion to dismiss. FCA cites to McKown v. Am. Honda Motor Co., No. CV 17-204-R, 2017 WL 4786086 (C.D. Cal. Jul. 11, 2017) and Preston v. Am. Honda Motor Co., No. 2:18-cv-00038, ECF #77, 2018 WL 5099507 (C.D. Cal. May 24, 2018) in support of its theory that the specific defective component of the defect must be pled to survive a motion to dismiss. Mot., Docket No. 21 at 6-7; Reply, Docket No. 30 at 3-4; see also Defendants RJN, Docket No. 27-1, Ex. A. However, McKown is distinguishable because in that case, the defect alleged included any and all vehicle components that could attract rodents, not just those that contain soy-based materials. McKown, 2017 WL 4786086, at \*2 ("The defect as alleged is not simply the use of soy-based components and parts, but rather those 'that attract rodents and other pests which eat and destroy' them."). Preston is similarly distinguishable because it was pled broadly. Defendants RJN, Docket No. 27-1, Ex. A at 3:15-16 ("Plaintiffs allege that 'whether the chewed wire itself is soy or bio-based is irrelevant because any soy or bio-based component nearby creates the rodentattractive environment."). Here, however, Milman pleads that soy- or bio-based components alone are at issue. See Compl., Docket No. 1. Unlike in Preston and McKown, the Complaint does not implicate non-soy or non-bio based components. Therefore, the Court agrees with Milman that the Complaint pleads the alleged defective components with the requisite level of specificity to survive a motion to dismiss.

Accordingly, the Court denies FCA's motion to dismiss all causes of action under Rule 8(a). However, as discussed below, the Court dismisses all of the causes of action on other grounds.

# 2. Express Warranty

Milman brings claims for breach of express warranty under California Commercial Code § 2313 and the Song-Beverly Act, California Civil Code §§ 1791.2 and 1793.2.

FCA moves to dismiss Milman's express warranty claims because (1) the Warranty does not cover design defects; (2) the Complaint does not allege breach of any express warranty; and (3) the Warranty is not unconscionable. Mot., Docket No. 21 at 8-10. Milman counters that (1) the Warranty is an ambiguous contract of adhesion which should be construed in her favor as the nondrafting party to cover design defects; (2) the Complaint adequately alleges breach of express warranty; (3) the Warranty is unconscionable; and (4) rodent damage is not an environmental condition expressly excluded from the Warranty. Opp'n, Docket No. 27 at 7-15.

# a. Scope of Warranty

The Warranty states in relevant part:

### A. What's Covered at No Cost to You

The Basic Warranty covers the cost of all parts and labor needed to repair any defective item on your vehicle that was supplied by Chrysler Motors – that is, <u>defective in material</u>, <u>workmanship</u>, <u>or factory preparation</u>. There is no list of covered parts since the only exception is tires. You pay nothing for these repairs. These Warranty repairs or adjustments – including all parts and labor connected with them – will be made by your dealer at no charge, using new or remanufactured parts.

Compl., Docket No. 1 ¶ 53 (emphasis in original).

Milman argues that the language in the Warranty covering defects in "factory preparation" is ambiguous as to whether it covers design defects. Opp'n, Docket No. 27 at 9-10. However, express warranties covering defects in "material, workmanship, or factory preparation" do not cover design

defects. See Garcia v. Chrysler Grp. LLC, 127 F.Supp.3d 212, 219 (S.D.N.Y. 2015) ("Notably, [a warranty covering defects in 'material, workmanship, or factory preparation'] does not cover design defects."); Digby Adler Grp., LLC v. Mercedes-Benz U.S.A., LLC, No. 14-cv-02349-TEH, 2015 WL 5138080, at \*5 (N.D. Cal. Sep. 1, 2015); Sater v. Chrysler Grp., No. EDCV 14-00700-VAP, 2015 WL 736273, at \*4 C.D. Cal. Feb. 20, 2015. Therefore, the Warranty unambiguously fails to cover design defects.

# b. Breach of Warranty

In order to allege breach of express warranty under California law, the buyer must allege that the seller: "(1) made an affirmation of fact or a promise, or otherwise described the goods; (2) the statement formed part of the basis of the bargain; (3) the express warranty was breached; (4) the plaintiff was harmed; and (5) the breach of warranty was a substantial factor causing the plaintiff's harm." Stearns v. Select Comfort Retail Corp., 763 F.Supp.2d 1128, 1142 (N.D. Cal. 2010).

\*6 "A design defect ... exists when the product is built in accordance with its intended specifications, but the design itself is inherently defective." Heber v. Toyota Motor Sales U.S.A., Inc., No. SACV 16–01525 AG (JCGx), 2018 WL 3104612, at \*4 (C.D. Cal. Jun. 11, 2018) (citing McCabe v. Am. Honda Motor Co., 100 Cal. App. 4th 111, 1120 (2002)).

The Court agrees with FCA that the Complaint alleges only a defect in design. See Compl., Docket No. 1 ¶¶ 8, 17, 18, 54. The Complaint does not allege that any individual wire or component was anomalously defective, but that the decision to use soy- or bio-based wiring is an inherent defect in the design of all Class Vehicles. See id. Furthermore, Milman does not dispute she has pled only a defect in design. Opp'n, Docket No. 27 at 6-7.

Milman also argues that she has adequately pled breach of express warranty based on FCA's statements in "various advertising media" about the "workmanship and reliability" of the Class Vehicles. Opp'n, Docket No. 27 at 11. FCA argues, and the Court agrees, that the Complaint does not allege facts to support this contention. Reply, Docket No. 5 at 5. The Complaint alleges that the "Warranty, as well as advertisements, brochures, and other statements in the media regarding the Class Vehicles, formed the basis of the bargain that was reached" when Milman purchased her

vehicle. Compl., Docket No. 1 ¶¶ 206-07. However, it does not allege the content of the representations contained in the advertisements upon which Milman relied in purchasing her allegedly defective vehicle. Nor does it allege when or where Milman encountered the advertisements. The Complaint's generalized, conclusory allegations are insufficient to support the claim that any statements outside the Warranty formed an express warranty on which Milman relied in purchasing her vehicle, and which FCA subsequently breached.

Because the repairs Milman seeks are not covered by express warranty, FCA cannot have committed a breach by refusing to pay for those repairs. Therefore, the Complaint fails to plead that FCA did not comply with its obligations under the Warranty.

# c. Unconscionability

Milman argues that, regardless of breach, the Warranty is unconscionable and unenforceable because, in the face of "grossly unequal bargaining power," FCA failed to disclose a known defect. Opp'n, Docket No. 27 at 13. Milman also argues that unconscionability is prematurely determined prior to discovery, and is more appropriately decided in a motion for summary judgment. <u>Id.</u> at 12.

FCA argues that the Complaint contains only "bald allegations of unconscionability," and that excluding design defects from a warranty is not unconscionable in and of itself. Mot., Docket No. 21 at 19. FCA also argues that Milman's claim of unconscionability is deficient because the Complaint fails to identify the specific provision purported to be unconscionable. Reply, Docket No. 30 at 6.

"Unconscionability generally has both a procedural and a substantive element." Oddo v. Arcoaire Air Conditioning & Heating, No. 8:15-CV-01985-CAS(), 2017 WL 372975, at \*9 (C.D. Cal. Jan. 24, 2017) (quoting Armendariz v. Found. Health Psychcare Servs., Inc., 24 Cal. 4th 83, 114, 99 Cal.Rptr.2d 745, 6 P.3d 669 (2000)). Procedural unconscionability focuses on two factors: oppression and surprise. Oddo, 2017 WL 372975, at \*10. Oppression arises from an inequality of bargaining power resulting in an absence of negotiation or meaningful choice, while surprise involves the extent to which agreed-upon terms are hidden in a prolix form drafted by the party seeking to enforce the contested terms. Id. Substantive unconscionability asks whether the results are so harsh as to "shock the conscience."

<u>Aron v. U-Haul Co. of California</u>, 143 Cal. App. 4th 796, 808, 49 Cal.Rptr.3d 555 (2006).

\*7 Here, the Complaint alleges that FCA's "attempt to disclaim or limit its express warranties vis-a-vis consumers is unconscionable and unenforceable ... because it knowingly sold a defective product without informing consumers about the Defect." Compl., Docket No. 1 ¶ 99. The Complaint further alleges that

[T]he application of (or refusal to permit coverage under) the Warranty is unconscionable and inadequate to protect Plaintiff and members of the Class given that Jeep knew of the Defect but failed and fails to disclose it. A gross disparity in bargaining power existed between Jeep and Class members, and Jeep knew or should have known that the Class Vehicles were defective at the time of sale and that the wiring systems would fail well before their useful lives.

<u>Id.</u> ¶¶ 214, 224.

These allegations are insufficient to plead a prima facie case of unconscionability. "Broad allegations of procedural unconscionability stating only that there was unequal bargaining power and ... a lack of meaningful choice relating to the limitations on the warranties are insufficient to state a prima facie claim for unconscionability." Resnick v. Hyundai Motor Am., Inc., No. CV 16-00593-BRO (PJWx), 2016 WL 9455016, at \*8 (C.D. Cal. Nov. 14, 2016) (internal quotation omitted). Furthermore, "any claim of oppression may be defeated if the complaining party had reasonably available alternative sources of supply from which to obtain the desired goods or services free from the terms claimed to be unconscionable." <u>Tietsworth v. Sears</u>, 720 F.Supp.2d 1123, 1139 (N.D. Cal. 2010) (citing Dean Witter Reynolds, Inc. v. Superior Court, 211 Cal. App. 3d 758, 768, 259 Cal. Rptr. 789 (1989)). Lastly, allegations of unconscionability are deficient where a plaintiff has "failed to plead which terms of the warrant[y] are unconscionable." Tietsworth, 720 F.Supp.2d at 1139 (citing Nordberg v. Trilegiant Corp., 445 F.Supp.2d 1082, 1099 (N.D. Cal. 2006)).

The Complaint fails to plead procedural unconscionability. The Complaint lacks any allegation of surprise, <u>i.e.</u>, that the terms of the Warranty were hidden or unclear at the time of sale. The Complaint also lacks any allegation that there were no alternative sources from which Milman could have obtained her vehicle free of the purportedly unconscionable Warranty. Lastly, the Complaint does not allege which Warranty provisions Milman contends are unconscionable.

Complaint The also fails to plead substantive unconscionability. Milman cites only non-binding, outof-circuit authority to support the proposition that it is substantively unconscionable for a manufacturer to limit warranties for consumer products with knowledge that the product is defective. See Opp'n, Docket No. 27 at 14. Furthermore, at least one court in this Circuit has dismissed an unconscionability claim alleging that a defendant limited an express warranty with knowledge of a defect. See, e.g., In re Sony Grand Wega KDF-E A10/A20 Series Rear Projection HDTV Television Litig., 758 F.Supp.2d 1077, 1100-01 (S.D. Cal. 2010).

While Milman is correct that unconscionability is often better suited for determination at summary judgment, where, as here, the Complaint does not allege facts supporting unconscionability, such claims may be dismissed. See, e.g., Tietsworth, 720 F.Supp.2d at 1139-40 (dismissing plaintiff's unconscionability claim). Therefore, the Court holds that the Complaint fails to plead that the Warranty was unconscionable.

#### d. Environmental Condition Exclusion

\*8 Milman argues that rodent damage is not an environmental condition excluded under the Warranty. Opp'n, Docket No. 27 at 14. However, the Court need not reach this issue in light of its determination that the Warranty does not cover the alleged design defect at all.

Section 3.2 of the Warranty, titled "Environmental Factors Not Covered," states: "Your warranties don't cover damage caused by environmental factors such as airborne fallout, chemicals, tree sap, salt, ocean spray, acid rain, and road hazards. Nor do your warranties cover damage caused by hailstorms, windstorms, tornadoes, sandstorms, lightning, floods, and earthquakes." Compl., Docket No. 1 ¶ 55.

Accordingly, the Court grants FCA's motion to dismiss the second, seventh, and ninth causes of action for breach of express warranty with leave to amend.

# 3. Implied Warranty

Milman brings claims for breach of the implied warranty of merchantability under California Commercial Code § 2313

and the Song-Beverly Act, California Civil Code §§ 1791.1 and 1792.

FCA argues that Milman's claims for breach of implied warranty should be dismissed because (1) the Complaint alleges no facts to support unmerchantability; (2) the claims rely on the actions of third parties; and (3) there was no vertical privity between Milman and FCA. Mot., Docket No. 21 at 10-12; Reply, Docket No. 30 at 7-9.

Milman argues in opposition that (1) the Complaint sufficiently alleges unmerchantability; (2) the claims do not rely on the actions of third parties, but the defect itself; (3) Milman pled vertical privity between herself and FCA based on an agency relationship between FCA and its authorized dealerships; and (4) in the alternative, the absence of privity does not bar Milman's implied warranty claims. Opp'n, Docket No. 27 at 15-21.

The implied warranty of merchantability requires that goods are "fit for the ordinary purposes for which such goods are used." Cal. Com. Code § 2314(2)(c). The implied warranty of merchantability is breached only if "the product [does] not possess even the most basic degree of fitness for ordinary use." Sims v. Kia Motors Am., Inc., No. SACV 13-1791 AG, 2014 WL 12558251, at \*3 (C.D. Cal. Oct. 8, 2014) (quoting Mocek v. Alfa Leisure, Inc., 114 Cal. App. 4th 402, 406, 7 Cal.Rptr.3d 546 (2003)). "At the pleading stage, Plaintiffs must ... allege either the manifestation of the defect in their product or a substantial certainty of manifestation." Sims, 2014 WL 12558251, at \*3 (citing Birdsong v. Apple, Inc., 590 F.3d 955, 959 (9th Cir. 2009)).

In motor vehicle cases, the basic inquiry is whether the vehicle was fit for driving. Lee v. Toyota Motor Sales, U.S.A., Inc., 992 F.Supp.2d 962, 979 (C.D. Cal. 2014); see also Carlson v. General Motors Corp., 883 F.2d 287, 297 (4th Cir.1989) ("Since cars are designed to provide transportation, the implied warranty of merchantability is simply a guarantee that they will operate in a safe condition and substantially free of defects. Thus, where a car can provide safe, reliable transportation, it is generally considered merchantable.").

As FCA notes, Milman's allegations of unmerchantability here are substantially similar to those pleaded in <u>Heber</u>. <u>See Heber</u>, 2018 WL 3104612, at \*\*1, 5. Like this case, <u>Heber</u> involved various warranty, fraud, and consumer protection claims based on the alleged use of soy-based materials in vehicles which purportedly created an increased risk of

rodent-inflicted damage. <u>Id.</u> at \*1. In <u>Heber</u>, the plaintiffs argued that the implied warranty was breached because the auto manufacturer's choice of materials created a latent defect, and that "rodent damage incurred because of Defendants' design and choice of materials render[ed] the Class Vehicles dangerous and/or inoperable." <u>Id.</u> at \*5. The court dismissed the implied warranty claim because

\*9 Assuming that a latent defect might give rise to an implied warranty claim, a "latent" defect, as the term might suggest, must be some defect within the vehicle itself. That's not what Plaintiffs allege. Plaintiffs implied warranty claim relies on the actions of a third party—those pesky rats. Only after the rats do their work does the vehicle become inoperable (if at all). Plaintiffs are, in effect, asking the Court to stretch the implied warranty of merchantability to include some promise that no external actor will later harm Plaintiffs' vehicles. The Court declines to extend the doctrine so far.

<u>Id.</u>

Milman attempts to distinguish this case because she has "pled that the inclusion of soy-based wires by Defendant 'attracts' rodents to come under the hood and feast on wires." Opp'n, Docket No. 27 at 18. However, it is unclear how this distinguishes <u>Heber</u>. Milman does not rebut how the actions of third parties, i.e. the rodents, are necessary to her claims.

Milman cites <u>Tsonev v. Kia Motors Am., Inc.</u>, No. SACV 16-01020-CJC(DFMx), 2016 WL 10000244, at \*4 (C.D. Cal. Nov. 9, 2016) for the proposition that allegations of wires that attract rodents causing the vehicle to operate improperly, <u>e.g.</u>, cause engine or airbag failure, are sufficient to state a claim for breach of implied warranty. <u>Id.</u> However, the Complaint contains no such allegations of engine or airbag failure. Rather, the Complaint alleges only broadly that rodent-attracting materials cause inoperability and a lack of functionality. <u>See</u> Compl., Docket No. 1 ¶ 35 (alleging that soy-based materials "compromis[e] the integrity of Class Vehicle electrical systems ... rendering Class Vehicles fully or partially inoperable"); <u>id.</u> ¶ 95 (alleging only that the defects causes vehicles "to fail prematurely and/or fail to function properly").

The Court finds Milman's arguments unpersuasive, and follows the rationale in <u>Heber</u>. Because the alleged inoperability forming the basis of Milman's claims for breach of implied warranty require the actions of third parties – the rodents – the claims are inadequately pleaded.

Accordingly, the Court dismisses the third, eighth, and tenth causes of action for breach of implied warranty without leave to amend.<sup>5</sup>

The parties also dispute whether there was privity between Milman and FCA, whether privity is required, and whether Milman qualifies as a third party beneficiary. See Mot., Docket No. 21 at 11-12; Opp'n, Docket No. 27 at 18-21; Reply, Docket No. 30 at 8-9. However, because third-party involvement requires dismissal of these claims with prejudice, these arguments are moot.

#### 4. MMWA

The Magnuson-Moss Warranty Act authorizes consumers to enforce the terms of express or implied warranties. 15 U.S.C. §§ 2301, et seq. Because Magnuson-Moss applies state warranty law, a plaintiff bringing a claim under Magnuson-Moss must adequately plead a warranty claim under state law. Daugherty v. Am. Honda Motor Co., Inc., 144 Cal. App. 4th 824, 832-33, 51 Cal.Rptr.3d 118 (2006); see also Daniel v. Ford Motor Co., 806 F.3d 1217, 1227 (9th Cir. 2015). Because Milman's state law warranty claims fail, her MMWA claim fails as well.

Accordingly, the Court grants FCA's motion to dismiss the first cause of action for violation of the MMWA.

## 5. Fraud-Based Claims

Milman's fraud-based claims are brought under (1) the fraudulent prong of the UCL; (2) the CLRA; (3) and commonlaw fraud and fraudulent concealment.

These claims may be analyzed together because all three must satisfy Rule 9(b). <u>Faulk v. Sears, Roebuck & Co.</u>, No. C 11-2159, 2011 WL 5521177, at \*5 (N.D. Cal. Nov. 14, 2011); <u>Kearns v. Ford Motor Co.</u>, 567 F.3d 1120, 1125 (9th Cir. 2009) (applying Rule 9(b) to UCL and CLRA claims). Thus, they will rise or fall together.<sup>6</sup>

To plead a claim under the "fraudulent" prong of the UCL, a plaintiff must show the defendant engaged in "fraudulent" conduct such that consumers are likely to be deceived by that conduct. <u>Id.</u> Fraudulent conduct may be based on a material omission. <u>Tietsworth</u>, 720 F.Supp. at 1136. The CLRA forbids "unfair methods of competition and unfair or deceptive acts or practices undertaken by any person in a transaction intended to result or that

results in the sale or lease of goods or services to any consumer." Cal. Civ. Code § 1770(a).

\*10 At the outset, the Court notes that the CLRA claim is procedurally barred. FCA argues that Milman did not file the required venue affidavit or satisfy pre-suit notice requirements under California Civil Code §§ 1780(d) and 1782(a). Mot., Docket No. 21 at 22-23; Reply, Docket No. 30 at 15. Milman failed to respond to these arguments in opposition, and thus concedes them. See Opp'n, Docket No. 27. Accordingly, the Court grants FCA's motion to dismiss the CLRA claim on these grounds.

FCA argues that Milman's fraud-based claims fail to meet the heightened pleading requirements of Rule 9(b). Mot., Docket No. 21 at 12-19. Milman argues that she has pled her fraud claims with sufficient particularity on theories of both fraudulent misrepresentation and fraudulent omission. Opp'n, Docket No. 27 at 21-27.

### a. Fraudulent Misrepresentation

FCA argues that Milman does not adequately plead affirmative misrepresentation because the Complaint fails to "identify the content of any statement, when or where it was made, who made it, or that she actually heard it in connection with her purchase decision." Mot., Docket No. 21 at 13.

Milman counters that the Complaint pleads affirmative misrepresentations regarding both (1) the Warranty, and (2) the "quality and workmanship of the Class Vehicles" through "various radio, television, print, and other advertising media." Opp'n, Docket No. 27 at 23.

Because the Court has determined that the Warranty does not cover the defects alleged, <u>supra</u> section II.B.2., Milman's fraud claims fail to the extent they are based on representations contained in the Warranty itself. Furthermore, Milman's allegations regarding representations in the media are broad and unspecific. The Complaint fails to identify what media Milman saw and relied on, when she saw the media, or what representations the media contained. Allegations that the representations concerned the "quality and workmanship" of Class Vehicles are insufficient to plead fraudulent misrepresentation in this context.

Therefore, Milman's fraud-based claims are dismissed to the extent they are based on fraudulent misrepresentations.

#### b. Fraudulent Omission

A fraudulent omission is actionable if the omission is "of a representation actually made by the defendant, or an omission of a fact the defendant was obliged to disclose." <u>Daugherty v. Am. Honda Motor Co., Inc., 144 Cal. App. 4th 824, 835, 51 Cal.Rptr.3d 118 (2006)</u>. To allege a duty to disclose, a plaintiff must show that the defendant (1) is in a fiduciary relationship with the plaintiff; (2) had exclusive knowledge of material facts not known to the plaintiff; (3) actively conceals a material fact from the plaintiff; or (4) makes partial representations but also suppresses some material fact. <u>LiMandri v. Judkins, 52 Cal. App. 4th 326, 336, 60 Cal.Rptr.2d 539 (1997)</u>.

Milman argues that the Complaint pleads facts to support a duty to disclose based on (1) exclusive knowledge, (2) active concealment, and (3) misleading partial representations. Opp'n, Docket No. 27 at 23-27. FCA argues that the Complaint fails to plead facts supporting a duty to disclose under any theory, and that Milman fails to plead an unreasonable safety hazard or actionable defect as required to state a claim for fraudulent omission in motor vehicle cases. Mot., Docket No. 21 at 15; Reply, Docket No. 30 at 11-14.

## i. Exclusive Knowledge

To demonstrate exclusive knowledge by a defendant, a plaintiff must allege that a "defendant was aware of a defect at the time of sale to survive a motion to dismiss." Wilson v. Hewlitt-Packard Co., 668 F.3d 1136, 1147 (9th Cir. 2012). Conclusory or generalized assertions that a defendant had exclusive knowledge of a defect are insufficient. Id. at 1146-47. Exclusive knowledge can be established when a defendant knew of a defect while the plaintiff did not and "given the nature of the defect, it was difficult to discover." In re MyFord Touch Consumer Litig., 46 F.Supp.3d 936, 960 (N.D. Cal. 2014) (citing Collins v. eMachines, Inc., 202 Cal. App. 4th 249, 256, 134 Cal.Rptr.3d 588 (2011)).

\*11 Milman argues that the Complaint sufficiently alleges FCA's exclusive knowledge of the defect based on "(1) [FCA's] own records of customers complaints; (2) dealership repair records; (3) NHTSA records; (4) warranty and postwarranty claims; (5) internal durability testing; and (6) other various sources." Compl., Docket No. 1 ¶ 39; Opp'n, Docket No. 27 at 24. Such "various sources" are alleged to include

"the high volume of media and consumer watchdog coverage of this issue." Compl., Docket No. 1 ¶ 48.

FCA argues that Milman's own allegations negate exclusive knowledge because the Complaint admits that there was "ample publicly available information about rodents' tendencies to gnaw on vehicle wires at the time she purchased her vehicle." Reply, Docket No. 30 at 11. The Court agrees. Milman must plead both that FCA had knowledge of the defect while she did not, and that the defect was "difficult to discover." See In re MyFord Touch Consumer Litig., 46 F.Supp.3d at 960. Milman alleges that the defect was reported in a "high volume" of media coverage. Compl., Docket No. 1 ¶ 48. Thus, the Complaint fails to plead that the defect was difficult to discover.

Therefore, Milman's claim for fraudulent omission under a theory of exclusive knowledge is dismissed.

#### ii. Active Concealment

To state a claim for active concealment, plaintiffs must plead "more than an omission;" rather, they must plead "affirmative acts of concealment; e.g., that the defendant 'sought to suppress information in the public domain or obscure the consumers' ability' to discover it." <a href="Taragan v. Nissan N. Am., Inc., No. C 09-3660 SBA, 2013 WL 3157918, at \*7 (N.D. Cal. Jun. 20, 2013)">No. C 09-3660 SBA, 2013 WL 3157918, at \*7 (N.D. Cal. Jun. 20, 2013)</a> (quoting <a href="Gray v. Toyota Motor Sales, U.S.A., No. CV 08-1690 PSG, 2012 WL 313703">No. CV 08-1690 PSG, 2012 WL 313703</a>, at \*10 (C.D. Cal. Jan. 23, 2012)).

Milman admits that allegations of nondisclosure alone are insufficient to maintain a claim for active concealment. Opp'n, Docket No. 27 at 25. Yet, Milman argues only that the Complaint alleges active concealment based on FCA "not disclosing" the alleged defect to customers. <u>Id.</u> Furthermore, the Complaint does not allege any facts to support FCA's active suppression of information in the public domain or of consumers' ability to discover information. Since mere nondisclosure does not constitute active concealment, this allegation is insufficient.

Therefore, Milman's claim for fraudulent omission under a theory of active concealment is dismissed.

### iii. Misleading Partial Representations

California recognizes a duty to disclose an alleged defect when the defendant "makes partial representations but also suppresses some material facts." Hobbs v. Brother Int'l Corp., No. CV 15–1866 PSG (MRWx), 2016 WL 7647674, at \*12 (C.D. Cal. Aug. 31, 2016) (citing LiMandri, 52 Cal. App. 4th at 336, 60 Cal.Rptr.2d 539).

Milman argues that she has pled misleading partial representations based on the "false" promises contained in the Warranty, combined with her being told at the dealership that the repair she sought "would not be reimbursed." Opp'n, Docket No. 27 at 25-26. FCA argues that the Complaint fails to allege any misleading affirmative representations, or any specific material facts that were withheld when such partial representation was made. Mot., Docket No. 21 at 17; Reply, Docket No. 30 at 13. Thus, FCA argues, Milman's partial representation claim is based only on the alleged failure to fulfill the "complete" representation made in the Warranty, and "the simple failure to fulfill a promise" is not a partial representation giving rise to a duty to disclose. Reply, Docket No. 30 at 13.

\*12 Milman has not pled affirmative statements which would cause a reasonable consumer to believe that the alleged defect would be repaired. The Court has already concluded that the Warranty doesn't cover the defects at issue in this case. Furthermore, there are no other affirmative statements pled or pointed to in Milman's opposition.

Therefore, Milman's claim for fraudulent omission under a theory of misleading partial representations is dismissed.

#### iv. Unreasonable Safety Hazard

In order to state a claim for failing to disclose a safety defect, Plaintiffs must allege (1) the existence of a design defect; (2) the existence of an unreasonable safety hazard; (3) a causal connection between the alleged defect and the alleged safety hazard; and (4) that the manufacturer knew of the defect at the time a sale was made. See Grodzitsky v. Am. Honda Motor Co., Inc., No. 2:12-1142-SVW-PLA, 2013 WL 2631326, at \*5 (C.D. Cal. Jun. 12, 2013) (citing Wilson, 668 F.3d at 1143-46). To establish a duty to disclose based on a safety issue, a plaintiff must allege "an instance of physical injury or a safety concern as well as a 'sufficient nexus' between the alleged defect and the safety issue." Elias v. Hewlett-Packard Co., 950 F.Supp.2d 1123, 1136 (N.D. Cal. 2013) (quoting Wilson, 668 F.3d at 1143-44).

FCA argues that the Complaint fails to plead an unreasonable safety hazard because Milman alleges that her own experience with the rodent-chewing defect in her vehicle resulted not in malfunction during normal operation, but only in "some undefined 'improper' operation that necessitate[d] a service visit when convenient." Mot., Docket No. 21 at 18. FCA argues that allegations of some "unspecified problem when operating her vehicle that was not serious enough to have diagnosed and repaired until it became convenient to do so" does not sufficiently plead that her vehicle malfunctioned in such a way as to leave her in peril. Reply, Docket No. 30 at 13-14. FCA also argues that these safety concerns are too "vague or speculative" to plead an unreasonable safety hazard, and that the alleged defect only exacerbates a preexisting risk of owning any vehicle - rodents chewing its components - rather than manifesting a "wholly abnormal condition." Id. at 18-19.

Milman argues in opposition that the Complaint sufficiently pleads a "legitimate safety threat" constituting more than speculative safety concerns, and that the injury risk need not have come to fruition if there is a sufficiently close nexus between the claimed defect and the alleged safety issue. Opp'n, Docket No. 27 at 26.

The Complaint alleges that "the safety concerns raised by wiring damage and failures in automobile electrical systems are obvious," posing "a legitimate threat to the safety" of Milman, class members, potential class-vehicle drivers, and other drivers on the road. Compl., Docket No. 1 ¶ 36. The Complaint also alleges that the defect "affects operability of Class Vehicles and creates safety concerns until manifestation of the defect." Id. ¶ 163(b).

Although the Court recognizes that a safety hazard need not have actually occurred to pose a sufficient risk, the Complaint's conclusory and speculative allegations do not sufficiently support the existence of an unreasonable safety risk. Milman does not cite to any facts regarding the degree to which her vehicle was unsafe, how it was unsafe, nor any particular safety risks which could result from the rodent-based defect. See Elias, 950 F.Supp.2d at 1136-37. Furthermore, Milman's own experience with the alleged defect does not portray an unreasonable safety hazard.

\*13 Therefore, Milman has not sufficient pled an unreasonable safety hazard giving rise to a duty to disclose.

# v. Actionable Defect

FCA argues that Milman fails to plead an actionable defect establishing a duty to disclose because the Complaint alleges a concern present in every vehicle – the risk of rodents chewing on vehicle components – and "rodents have been chewing on vehicle components forever." Mot., Docket No. 21 at 19. Since the soy- or bio-based components are not alleged "to do anything that they were not designed to do," FCA argues, "there are no allegations that the wires/components have malfunctioned in any way." Reply, Docket No. 30 at 14. Furthermore, FCA argues that Milman provides no support for the notion that a failure to prevent an outside force from causing a malfunction can constitute an actionable defect. <u>Id.</u> Thus, FCA argues that Milman fails to plead an actionable defect in the consumer fraud context. <u>Id.</u>; Mot., Docket No. 21 at 19.

Milman argues that FCA's alleged use of soy-based or bio-based components amounts to an actionable defect. Opp'n, Docket No. 27 at 26-27. Milman argues that the Complaint alleges that the use of such materials attracts rodents, who "feast on the wires making the Class Vehicles unsafe and inoperable," and that thus the soy- and bio-based components are doing something they weren't intended to do. <u>Id.</u>

FCA cites to <u>Azoulai v. BMW of N. Am. LLC</u>, No. 16-CV-00589-BLF, 2017 WL 1354781 (N.D. Cal. Apr. 13, 2017) and <u>Birdsong v. Apple, Inc.</u>, 590 F.3d 955 (9th Cir. 2009) in support of this argument. In <u>Azoulai</u>, a plaintiff lacked standing to assert consumer fraud based on the claimed defect – that an automatic door closing system lacked a sensor to detect fingers in the doors so as to prevent injury. <u>Azoulai</u>, 2017 WL 1354781 at \*1. The court reasoned that

the lack of a sensor in the ... system does not constitute a design defect in the consumer fraud context. Indeed, neither the SAC nor Plaintiffs' opposition articulates a plausible legal theory of defect: the SCA did not malfunction or fail and Plaintiffs did not discuss any theories, such as those from the products liability context, whereby a properly-functioning product could nevertheless be deemed defectively designed.

<u>Id.</u> at \*6.

Similarly, in <u>Birdsong</u>, the Ninth Circuit declined to recognize a claimed defect in iPods which could be played at volume levels dangerous to hearing, yet which had no isolating or cancelling properties, nor any meter informing the user that the volume was being played at dangerous levels. Birdsong, 590 F.3d at 958-59. The court reasoned that plaintiffs "merely suggest[ed] possible changes to the iPod which they believe[d] would make the product safer," which was insufficient to plead a cognizable defect because it was "premised on the loss of a 'safety' benefit that was not part of the bargain to begin with." Id. at 959, 961-62.

Here, the Complaint alleges that rodents are "uniquely attracted" to the soy- and bio-based materials FCA allegedly uses in its vehicle's wiring systems. Compl., Docket No. 1 ¶ 4. The Court agrees with Milman that this alleged design utilizing soy- and bio-based vehicle components does more than simply fail to prevent the risks of rodent-damage present in every vehicle. Rather, it is alleged to attract rodents "uniquely." However, like Azoulai and Birdsong, Milman fails to allege either (1) that the soy- or bio-based components malfunctioned in some way, or (2) any theory from outside the consumer-fraud context that the failure to prevent an outside force from causing a malfunction can be an actionable defect. Therefore, Milman fails to plead an actionable defect in the consumer fraud context.

\*14 Accordingly, the Court grants FCA's motion to dismiss the fourth cause of action for violation of the UCL to the extent it is based on the fraudulent prong, the sixth cause of action for violation of the CLRA, and the eleventh cause of action for fraud and fraudulent concealment with leave to amend.

### 6. UCL

#### a. Fraudulent Prong

As discussed above, claims brought under the fraudulent prong of the UCL sound in fraud and must satisfy Rule 9(b). Kearns, 567 F.3d at 1125. The Court has already determined that Milman's claims fail to meet the heightened pleading requirements of Rule 9(b). Therefore, Milman's claim alleging fraudulent business practices is dismissed.<sup>7</sup>

FCA also argues that Milman's UCL claim should fail under all three prongs because the claim alleges a "unified course of fraudulent conduct," and thus the claim as a whole must satisfy Rule 9(b). Vess, 317 F.3d at 1103-04; see also Opp'n, Docket No. 27 at 27-28. However, as discussed infra, the claims under the

"unfair" and "unlawful" prongs of the UCL are dismissed for independent reasons. Thus, FCA's unified course of conduct argument is moot.

# b. Unfairness Prong

The legal standard applied to "unfair" UCL claims is unsettled. Yanting Zhang v. Superior Court, 57 Cal. 4th 364, 380 n.9, 159 Cal.Rptr.3d 672, 304 P.3d 163 (2013) (declining to resolve conflicting lower court opinions). A number of tests have been applied by California courts. Under the balancing test, courts weigh "the utility of the defendant's conduct against the gravity of the harm to the alleged victim." Davis v. HSBC Bank Nevada, N.A., 691 F.3d 1152, 1169 (9th Cir. 2012) (citation omitted). Under the public policy test, courts focus on whether the challenged conduct violates a public policy that is tethered to specific constitutional, statutory or regulatory provisions. See Aleksick v. 7-Eleven, Inc., 205 Cal. App. 4th 1176, 1192, 140 Cal.Rptr.3d 796 (2012).

FCA argues that Milman fails to allege that FCA's conduct violates a legislatively declared policy or allowed it to unfairly compete. Mot., Docket No. 21 at 30. Furthermore, FCA argues that conclusory allegations of "unfair competition" are inconsistent with allegations that other manufacturers in the industry use soy- and bio-based materials, i.e., that use of such materials is standard in the industry. Id. at 21; Reply, Docket No. 30 at 14.

Milman counters that she has pled the "unfairness" prong successfully because she alleges that FCA's conduct was "immoral, unethical, and oppressive, and ... not outweighed by any countervailing benefits to consumers." Opp'n, Docket No. 27 at 28; see also Compl., Docket No. 1¶144.

The Court agrees with FCA that Milman's allegations supporting violation of the UCL's "unfairness" prong are conclusory and devoid of factual support. Milman's allegations fail to identify any legislatively declared policy to which her claims are tethered. The Complaint also fails to allege how the use of soy- or bio-based materials is anti-competitive, or facts relating to the utility of FCA's conduct being outweighed by the gravity of harm suffered by consumers. Therefore, Milman's claim alleging unfair business practices is dismissed.

c. Unlawful Prong

The "unlawful" prong of the UCL treats violations of other federal, state, regulatory, or court-made law as unlawful business practices independently actionable under state law. Nat'l Rural Telecomm. Coop. v. DIRECTV, Inc., 319 F.Supp.2d 1059, 1074 (C.D. Cal. 2003) (citation omitted). FCA argues that Milman's "unlawful" claim should be dismissed because it is based on her other pleaded claims which all fail. Mot., Docket No. 21 at 21. The Court agrees. Therefore, Milman's claim alleging unlawful business practices is dismissed.

\*15 Accordingly, the Court grants FCA's motion to dismiss the fifth cause of action for violations of the UCL with leave to amend.

# 7. Declaratory Judgment

Under the Declaratory Judgment Act, federal courts have discretion to "declare the rights and other legal relations of any interested party seeking such declaration whether or not further relief is or could be sought." 28 U.S.C. § 2201. A claim for relief under the Declaratory Judgment Act requires a dispute that is: (1) "definite and concrete, touching the legal relations of parties having adverse legal interests"; (2) "real and substantial"; and (3) "admit[ting] of specific relief through a decree of a conclusive character, as distinguished from an opinion advising what the law would be upon a hypothetical state of facts." MedImmune, Inc. v. Genentech, Inc., 549 U.S. 118, 127, 127 S.Ct. 764, 166 L.Ed.2d 604 (2007) (internal quotation marks and citation omitted). The Declaratory Judgment Act confers "unique and substantial discretion" upon district courts "in deciding whether to declare the rights of litigants." Wilton v. Seven Falls Co., 515 U.S. 277, 286, 115 S.Ct. 2137, 132 L.Ed.2d 214 (1995).

FCA argues, and the Court agrees, that Milman effectively seeks a declaration that FCA is liable for breach of express warranty. Mot., Docket No. 21 at 23; Compl ¶¶ 117-18. However, in light of the foregoing analysis, the Court concludes that Milman fails to state any claim and thus there is no actual controversy on which to predicate declaratory relief. See 28 U.S.C. § 2201.

Accordingly, the Court grants FCA's motion to dismiss the fourth cause of action for declaratory relief with leave to amend.

# 8. Equitable Relief

"A plaintiff seeking equitable relief in California must establish that there is no adequate remedy at law." Gomez v. Jelly Belly Candy Co., No. 17-00575-CJC(FFM), 2017 WL 8941167, at \*1 (C.D. Cal. Aug. 18, 2017) (citations omitted); see also Schroeder v. United States, 569 F.3d 956, 963 (9th Cir. 2009) ("[E]quitable relief is not appropriate where an adequate remedy exists at law."). Here, the Complaint seeks both damages and equitable relief in the form of unjust enrichment. Compl., Docket No. 1 ¶ 10. The Complaint also asks for "appropriate curative notice regarding the existence and cause of the defect" for each cause of action except the fifth cause of action under the UCL. See id., Prayer for Relief at 46-51. Milman does not challenge that she must allege that she lacks an adequate remedy at law, but instead argues that the Complaint pleads unjust enrichment "in the alternative." Opp'n, Docket No. 27 at 30.

The Complaint alleges in a conclusory fashion that Milman has no "adequate remedy at law to redress the injuries which she has suffered" as a result of FCA's "unfair, unlawful and/or fraudulent business practices." Compl., Docket No. 1 ¶ 147.

FCA argues that the Complaint does not contain any allegation suggesting that Milman could not be made whole by the payment of money damages. Mot., Docket No. 21 at 24. FCA also argues that Milman's equitable claims are based on "the exact same conduct" as those seeking monetary relief. Id. The Court agrees. The Complaint fails to allege how monetary damages – the quintessential remedy at law – are unavailable

to Milman. Nor does Milman's opposition make any argument as to how Milman has no adequate remedy at law. See Opp'n, Docket No. 27 at 30. There is no indication that money damages would be too speculative or otherwise inadequate in this case. Furthermore, Milman's argument that her pleading for equitable relief is nonetheless sufficient because it was made "in the alternative" is unavailing.

\*16 Accordingly, the Court grants FCA's motion to dismiss Milman's claims for equitable relief with leave to amend.

# III. Motion To Strike

Under the analysis above, the Court grants FCA's motion to dismiss. Therefore, FCA's motion to strike is moot.

#### IV. Conclusion

For the foregoing reasons, the Court **grants** FCA's motion to dismiss with leave to amend except as to Milman's implied warranty claims, which are dismissed without leave to amend.

# IT IS SO ORDERED.

# **All Citations**

Not Reported in Fed. Supp., 2018 WL 5867481

**End of Document** 

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# **Tab 25**

2020 WL 3468250 United States District Court, D. New Jersey.

Garner RICKMAN, Ziwen Li, Gary Reising, Jacob Biggins, Tom Hoffman, Alexander Vandamme, Seth Davis, Charles Chapman, Charles Rogers, Ion Nicolescu, Werner Rogmans, Erica Olson, Algredo Arias, Jesse White, Razmir Avic, Rickey Evans, Mark Messina, Lukas Wildner, Miguel Fragoso, Mark Smith, William Berbaum, Kyle Kern, Eric Stenglein, Carlos Buendia, Tahani Ibrahim, John Saviano, Gene Quint, Brian Hembling, Irving Cohen, Christine Griffith, Tarrah Pee, Darshan Patel, Brian Beckner, Joshua Hu, Jeffrey Price, Dean Werner, Eric Sanchez, Charles Campbell, Angela Hughes, James Turner, Ellis Goldfrit, Chad Maccanelli, and Salomon Campos, individually and on behalf of all others similarly situated, Plaintiffs,

BMW OF NORTH AMERICA, Bayerische Motoren Werke Aktiengesellschaft (BMW A.G.), Robert Bosch GmbH, and Robert Bosch LLC, Defendants.

v.

Civ. No. 18-4363(KM) (JBC) | Signed 06/25/2020

# **Attorneys and Law Firms**

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NY, Amy Danielle Luria, Michael D. Critchley, Critchley, Kinum & DeNoia, LLC, Roseland, NJ, for Defendants.

# **OPINION**

# KEVIN MCNULTY, U.S.D.J.:

\*1 The named plaintiffs in this case represent a putative class of car buyers who each allegedly own a BMW X5 or BMW 335D vehicle. On behalf of the class, the named plaintiffs sued BMW of North America ("BMW USA"); Bayerische Motoren Werke Aktiengesellschaft ("BMW AG") (together, "BMW"); Robert Bosch GmbH; and Robert Bosch LLC (together, "Bosch") for their alleged roles in the clean-diesel emissions scandal. Plaintiffs' first amended complaint ("1AC", DE 65)<sup>1</sup> asserts one count under the federal RICO statute and seventy-eight counts under the laws of various states.

"DE —" refers to the docket entry in this case.

Now before the Court are the motions to dismiss, pursuant to Fed. R. Civ. P. 12(b)(6), of defendants BMW USA (DE 68) and Robert Bosch LLC (DE 69). For the following reasons, the motions are **GRANTED** in part and **DENIED** in part. Plaintiffs have failed to allege standing to bring a claim under the federal Racketeer Influenced and Corrupt Organizations Act ("RICO"), 18 U.S.C. § 1962. Because amendment would appear to be futile, the portion of the complaint that purports to state a claim for RICO relief (Count 1) is **DISMISSED**. Because federal-court jurisdiction is unaffected by that dismissal, Plaintiffs may continue to prosecute their state-law claims (Counts 2–79).

# I. BACKGROUND<sup>2</sup>

For purposes of this motion, the facts alleged in the first amended complaint, not yet tested by any fact finder, are assumed to be true.

Familiarity with this matter is presumed; I write for the parties and do not repeat the factual background described in my June 27, 2019 opinion (DE 59), which dismissed the original consolidated class action complaint. Instead, I will briefly summarize the new allegations contained in the first amended complaint.

# A. New Allegations, Generally

The linchpin issue that doomed the consolidated class action complaint (DE 26) was the lack of "a straightforward allegation that an identified plaintiff bought a car which. when tested or analyzed, turned out to contain a defeat device." (DE 59 at 2). Instead, the consolidated class action complaint relied on a single X5 vehicle that "seem[ed] to be proffered as an exemplar." (DE 59 at 2). The first amended complaint also does not allege facts to establish that any named plaintiff's car contained a defeat device. It is true that the new pleadings contain more robust allegations concerning the testing and analysis of five "clean diesel" and one gasoline vehicle. (1AC ¶ 163). Still, no plaintiff claims to have owned any of the tested vehicles; instead, Plaintiffs' theory is that each vehicle is representative of the entire line of cars. (1AC ¶¶ 3 &73).

Plaintiffs emphasize that when a car manufacturer like BMW seeks regulatory approval for a new vehicle, the manufacturers submit to the EPA a single vehicle to stand in for the entire model line. (1AC  $\P\P$  3 & 173). The theory is that each subject vehicle is materially and fundamentally identical to every other vehicle in the fleet, and therefore is properly the subject of the clean diesel testing fraud allegations. That theory is the foundation upon which the first amended complaint seeks to cure the deficiencies of the previously dismissed consolidated class action complaint. To that end, Plaintiffs note that after the class action complaint was dismissed, their experts performed tests using the portable emission measurement system ("PEMS") and a chassis dynamometer on several additional vehiclesalthough, again, none in particular is alleged to have belonged to any named plaintiff.

- \*2 The tested vehicles consisted of two 2012 BMW X5s, one 2011 BMW X5, two 2011 BMW 335ds, and a gasolinepowered 2012 X5.3 (1AC ¶ 163 & 169–252). The first amended complaint also includes new information about the vehicles that were tested, including allegations that their mileage was close to the certification standard, that they had been properly maintained, and that none had any emissionsystem faults. (1AC ¶¶ 169, 171 & 172).
- Plaintiffs allege that for all material purposes, the tested models represent all makes and model years of the vehicles at issue here. (1AC ¶¶ 2, 3 & 172). All models at issue share a common diesel engine. (1AC ¶¶ 101–15).

Plaintiffs maintain that the first amended complaint sets forth detailed, particularized allegations of:

- (1) tests of five diesel vehicles (1AC ¶¶ 3, 20, 125–28 & 169–
- (2) PEMS testing (1AC ¶¶ 2, 3, 4, 5, 17, 163 & 186–252);
- (3) chassis dynamometer testing (1AC ¶¶ 17 & 174–85);
- (4) with the test results showing use of defeat devices (1AC ¶¶ 18–24 & 174–252);
- (5) the operation of the defeat devices (1AC ¶¶ 25 & 253– 66); and
- (6) Defendants' manipulation of the EDC17 system (1AC ¶¶ 25, 80, 84, 85, 203, 204, 253-66 & 269-308).

Plaintiffs have also submitted to the Court scientific literature. reports, and testing accounts from independent entities that purport to show that most "clean diesel" vehicles emit far more pollution on the road than in laboratory tests. (1AC ¶¶ 322-32). The first amended complaint also vouches for the reliability of the PEMS testing system. 4 (1AC ¶¶ 4 & 152– 68).

European vehicle-emissions regulators use PEMS to test real-world driving conditions. (1AC ¶ 154). The EPA and the California Air Resources Board ("CARB") also use PEMS testing for their heavy-duty in-use compliance program to measure emissions against the not-to-exceed standards. The EPA and the CARB widely use PEMS to evaluate vehicles for defeat devices. (1AC ¶ 154).

Plaintiffs allege that their scientific evidence confirms the superior accuracy of PEMS testing as compared with chassis dynamometer testing.<sup>5</sup> The first amended complaint focuses on the weaknesses inherent in chassis dynamometer testing. These weaknesses of chassis dynamometer testing include that (1) during testing, the front wheels move but do not turn, which does not happen in real-world driving conditions; (2) on a two-wheel drive vehicle, the driven wheels are moving but the non-driven wheels are not; and (3) on a vehicle equipped with GPS, the vehicle's wheels move while the GPS position does not change. (1AC ¶ 166). According to Plaintiffs, an engine can be designed to detect that it is being tested on a chassis dynamometer, but the same is not true as to PEMS testing. Thus, according to Plaintiffs, "PEMS is not only accurate for detection and quantification of defeat devices, it is essential." (1AC ¶ 166).

One study concluded that because PEMS testing is designed for—and is conducted on the road in actual driving—it is in certain respects *more accurate* than chassis dynamometer testing. (DE ¶ 160).

Plaintiffs subjected all five subject vehicles to laboratory and real-world testing. The vehicles were first tested on a chassis dynamometer, adhering to federal test protocols in a CFR-compliant laboratory. (1AC ¶¶ 125–28 & 174). In this laboratory testing environment, the five vehicles all met or approached emissions standards. (1AC ¶¶ 180–85). During on-road PEMS testing, however, the vehicles did not meet the standard. The first amended complaint alleges that the defeat device drove the vehicles' on-road NOx emissions dramatically higher. Specifically, under city driving conditions, the vehicles' emissions were 1.4 to 7.5 times the standard and, at times, 9 to 73 times the standard. (1AC ¶¶ 19 & 192). Under highway-driving conditions, all but one diesel vehicle exceeded the standards. The 2012 X5, for example, exceeded the standard by a multiple of 3.4. (1AC¶ 195). The gasoline-powered BMW X5, by contrast, had an average NOx emission rate below the emissions standard in both chassis dynamometer and PEMS testing. (1AC ¶ 192).

\*3 Plaintiffs also claim that the first amended complaint adequately alleges the use of a temperature defeat device, embodied in software programming. (1AC ¶ 197) The temperatures in vehicle test-certification cycles must be between 68°F and 86°F, but the first amended complaint details how emissions controls are turned down or off in temperatures outside that range. (1AC ¶¶ 196–210). According to Plaintiffs, PEMS testing revealed the use of a temperature defeat device, yielding emissions as high as 526 mg/mile. (1AC ¶¶ 196–200).

The first amended complaint also alleges that the subject vehicles can reduce NOx to meet emissions standards so long as the effectiveness of the emissions-control system is not otherwise reduced, such as by instruction from the EDC17. (1AC ¶ 213 & 214). It also contains allegations that describe how the emissions systems were disabled. (1AC ¶ 215–19). Specifically, by isolating and testing laboratory-like conditions during PEMS testing, Plaintiffs' experts concluded that the subject vehicles are able to detect the certification test cycle and adjust the emissions performance when the EDC17 "knows" the test cycle is not being run. (1AC ¶ 218).

Moreover, the first amended complaint alleges that Plaintiffs' PEMS tests showed increased emissions during cold-start and hot-start conditions, and that the tested vehicles did not

pass PEMS testing during the passive regeneration phase that removes diesel particulate matter.<sup>6</sup> (1AC ¶¶ 21–24, 220–28, 241 & 304).

Active regenerations should theoretically occur infrequently because of the increase in emissions and fuel economy impacts. (1AC ¶ 22). But expert testing reveals active regeneration far in excess of the permissible frequency, which is above the permissible certification frequency for all the tested diesel models. (1AC ¶¶ 21–24, 221 & 247–50).

All of these new allegations taken together, Plaintiffs assert, cure the deficiencies identified in the consolidated class action complaint.

#### B. New Allegations Directed at Bosch

The first amended complaint also contains revised allegations regarding Bosch's participation in the scheme. According to Plaintiffs, Bosch in 2006 introduced the EDC17 as the "brain of diesel injection" that "controls every parameter that is important for effective, low-emission combustion," because it wanted to enter the lucrative diesel market. (1AC¶ 269). The EDC17 is a proprietary system over which Bosch exerts complete control to prevent its clients from changing the software without Bosch's participation. (1AC¶ 258 & 271–73).

Plaintiffs allege that Bosch's control over the software allowed BMW to reduce or turn off emissions controls when the vehicle sensed it was not in a testing environment. (1AC ¶ 6 & 260). Moreover, Bosch actively marketed clean diesel technology throughout the United States. (DE ¶¶ 25 & 289– 94). Plaintiffs allege that Bosch participated in the fraudulent scheme by manufacturing, installing, testing, modifying, and supplying the EDC17, which operated as a defeat device and turned off or turned down emissions controls in the BMW vehicles. (1AC ¶ 373). Bosch also allegedly concealed the defeat devices in U.S. documentation and in communications with U.S. regulators. (1AC ¶ 373). Almost all manufacturers to whom Bosch sold the EDC17 are now known to have used defeat devices and to have misled consumers. Bosch was involved in the Volkswagen scandal, actively working to conceal manipulation in the software that it programmed in a collaborative scheme with Volkswagen. (1AC ¶¶ 83-84 & 267-83).

# C. Procedural History

\*4 On June 27, 2019, I filed an opinion (DE 59) and order (DE 60), dismissing without prejudice the consolidated class action complaint (DE 26). As discussed in that opinion, the dismissal rested on Plaintiffs' failure to allege Article III standing, and was entered without prejudice to the filing of an amended complaint. On September 20, 2019, Plaintiffs filed the first amended complaint. (DE 65). BMW and Bosch again moved to dismiss. (DE 68 & 69). BMW's motion to dismiss is accompanied by a request for judicial notice and seventeen exhibits, which consist primarily of news articles discussing BMW's role (or lack thereof) in the clean diesel emissions scandal. (DE 68-3 through 68-20).

# II. DISCUSSION AND ANALYSIS

This Court has subject matter jurisdiction over this action under 28 U.S.C. § 1331 to the extent that Plaintiffs' claims arise under the Racketeer Influenced and Corrupt Organizations Act ("RICO"), 18 U.S.C. § 1962. The Court has supplemental jurisdiction over Plaintiffs' state-law claims under 28 U.S.C. § 1367.

Alternatively, this Court has ordinary diversity jurisdiction because Plaintiffs and Defendants reside in different states and the amount in controversy exceeds \$75,000. 28 U.S.C. 1332(a). This Court also has original diversity jurisdiction over this lawsuit pursuant to the pursuant to the Class Action Fairness Act of 2005. 28 U.S.C. § 1332(d). Plaintiffs and Defendants are citizens of different states; there are more than one-hundred members of the class; the aggregate amount in controversy exceeds \$5 million; and class members reside across the United States.

#### A. Standard of Review

Federal courts are courts of limited jurisdiction which are confined to the adjudication of "cases" or "controversies" as permitted by Article III of the Constitution. See U.S. Const., Art. III, § 2. The case-or-controversy requirement requires that a plaintiff possess constitutional standing. Taliaferro v. Darby Twp. Zoning Bd., 458 F.3d 181, 188 (3d Cir. 2006). For a plaintiff to have constitutional standing, the following three elements must be present: "the plaintiff must have (1) suffered an injury in fact, (2) that is fairly traceable to the challenged conduct of the defendant, and (3) that is likely to be redressed by a favorable judicial decision." Spokeo, Inc. v. Robbins, 136 S. Ct. 1540, 1547 (2016); In re Nickelodeon Consumer Privacy Litig., 827 F.3d 262, 272 (3d Cir. 2016). "The plaintiff, as the party invoking federal jurisdiction, bears the burden of establishing these elements." Spokeo, 136 S. Ct.

1540, 1547. "Absent Article III standing, a federal court does not have subject matter jurisdiction to address a plaintiff's claims, and they must be dismissed." *Taliaferro*, 458 F.3d 181, 188. Consequently, a motion to dismiss for lack of standing is properly brought under Federal Rule of Civil Procedure 12(b) (1). *Constitution Party of Pa. v. Aichele*, 757 F.3d 347, 357 (3d Cir. 2014); *In re Schering Plough Corp. Intron/Temodar Consumer Class Action*, 678 F.3d 235, 243 (3d Cir. 2012).

Federal Rule of Civil Procedure 12(b)(1) governs jurisdictional challenges to a complaint. These may be either facial or factual attacks. See 2 Moore's Federal Practice § 12.30[4] (3d ed. 2007); Davis v. Wells Fargo, 824 F.3d 333, 346 (3d Cir. 2016). A facial challenge asserts that the complaint does not allege sufficient grounds to establish subject matter jurisdiction. Lincoln Ben. Life Co. v. AEI Life, LLC, 800 F.3d 99, 105 (3d Cir. 2015); Iwanowa v. Ford Motor Co., 67 F. Supp. 2d 424, 438 (D.N.J. 1999). "In reviewing a facial attack, the court must only consider the allegations of the complaint and documents referenced therein and attached thereto, in the light most favorable to the plaintiff." Lincoln Ben. Life, 800 F.3d at 105 (citing Gould Elecs. Inc. v. United States, 220 F.3d 169, 176 (3d Cir. 2000)). As to a facial jurisdictional attack, then, the standard is similar to the one that applies to an ordinary motion to dismiss under Federal Rule of Civil Procedure 12(b)(6).

- A factual attack, on the other hand, permits the Court to consider evidence extrinsic to the pleadings. *Lincoln Ben. Life*, 800 F.3d at 105; *Gould Elecs. Inc. v. United States*, 220 F.3d 169, 178 (3d Cir. 2000), *holding modified on other grounds by Simon v. United States*, 341 F.3d 193 (3d Cir. 2003).
- \*5 Federal Rule of Civil Procedure 12(b)(6) provides for the dismissal of a complaint, in whole or in part, if it fails to state a claim upon which relief can be granted. The defendant, as the moving party, bears the burden of showing that no claim has been stated. *Animal Science Products, Inc. v. China Minmetals Corp.*, 654 F.3d 462, 469 n. 9 (3d Cir. 2011). For the purposes of a motion to dismiss, the facts alleged in the complaint are accepted as true and all reasonable inferences are drawn in favor of the plaintiff. *N.J. Carpenters & the Trustees Thereof v. Tishman Constr. Corp. of N.J.*, 760 F.3d 297, 302 (3d Cir. 2014).

Federal Rule of Civil Procedure 8(a) does not require that a complaint contain detailed factual allegations. Nevertheless, "a plaintiff's obligation to provide the 'grounds' of his 'entitlement to relief' requires more than labels and

conclusions, and a formulaic recitation of the elements of a cause of action will not do." Bell Atl. Corp. v. Twombly, 550 U.S. 544, 555 (2007). Thus, the complaint's factual allegations must be sufficient to raise a plaintiff's right to relief above a speculative level, so that a claim is "plausible on its face." Id. at 570; see also W. Run Student Hous. Assocs., LLC v. Huntington Nat'l Bank, 712 F.3d 165, 169 (3d Cir. 2013). That facial-plausibility standard is met "when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009) (citing Twombly, 550 U.S. 544, 556). While "[t]he plausibility standard is not akin to a 'probability requirement' ... it asks for more than a sheer possibility." Igbal, 556 U.S. 662, 678.

With respect to allegations of fraud, "a party must state with particularity the circumstances constituting fraud," although "intent, knowledge, and other conditions of a person's mind may be alleged generally." Fed. R. Civ. P. 9(b); see also U.S. ex rel. Moore & Co., P.A. v. Majestic Blue Fisheries, LLC, 812 F.3d 294, 307 (3d Cir. 2016) ("A plaintiff alleging fraud must therefore support its allegations 'with all of the essential factual background that would accompany the first paragraph of any newspaper story—that is, the who, what, when, where and how of the events at issue.' " (quoting *In re Rockefeller* Ctr. Props., Inc. Securities Litig., 311 F.3d 198, 217 (3d Cir. 2002))). In doing so, "a party must plead [its] claim with enough particularity to place defendants on notice of the precise misconduct with which they are charged." United States ex rel. Petras v. Simparel, Inc., 857 F.3d 497, 502 (3d Cir. 2017) (internal quotation and citation omitted).

# **B. Article III Standing**

In this Court's opinion dismissing the consolidated class action complaint (DE 26), I determined, for two reasons, that Plaintiffs' reliance on the test results of single vehicle was insufficient to establish standing:

I find inadequate the allegation that the Plaintiffs' vehicles contain a defeat device for two primary reasons. First, it depends on testing of a single vehicle which revealed discrepancies between laboratory and on-road emissions results, from which plaintiffs somewhat speculatively infer that the vehicle contained a defeat device. Second, it relies on a further inference that the tested vehicle is a valid exemplar—i.e., that because it contained a defeat device, then the Plaintiffs' vehicles, too, must have contained such a device.

\*6 (DE 59 at 16). Now, in the first amended complaint, Plaintiffs return to this Court having tested what they allege are five exemplar vehicles. (1AC). And again, BMW and Bosch challenge the sufficiency of the pleadings and assert that Plaintiffs have not established standing to bring their claims. (DE 68 & 69).

BMW broadly attacks the sufficiency of Plaintiffs' allegations. Specifically, BMW alleges that the first amended complaint does not allege an injury in fact because (1) none of Plaintiffs' vehicles were tested (DE 68-1 at 21-22); (2) the first amended complaint does not allege corroborating facts (DE 68-1 at 22-24); and (3) the first amended complaint does not identify a defeat device (DE 68-1 at 24-25). BMW also notes that some tested vehicle arguably passed PEMS testing. (DE 68-1 at 25-28). Finally, BMW insists that there is no injury fairly traceable to BMW's conduct. (DE 68-1 at 31-34).

Bosch generally adopts these arguments that, adding only that any overpayment by Plaintiffs would have been to BMWnot Bosch—and that Bosch had no control over the subject vehicles. (DE 69-1 at 5-6).

Defendants contend that Plaintiffs still lack standing because they have not alleged that any tested vehicle belonged to any plaintiff. However, Plaintiffs have alleged that the five tested vehicles represent, and are substantially identical to, those owned by Plaintiffs and which are the subject of Defendants' alleged scheme. The purpose of Rule 8(a) is to give a defendant "fair notice" of the claim against him and her, and the allegations here do just that. The allegations contained in the first amended complaint are sufficient to permit a plausible inference that BMW's vehicles, including those purchased by Plaintiffs, contained defeat devices.

Defendants also note that Plaintiffs do not allege specifics as to the driving history or maintenance record of the tested vehicles. This deficiency, they conclude, dooms Plaintiffs case, presumably under the theory that some intervening event could have caused the heightened emissions in Plaintiffs' vehicles. While some such intervening cause may favor Defendants' position at a later point in the proceeding, for now, Plaintiffs' allegations regarding ownership of specific BMW models is sufficient to notify Defendants which of its cars are alleged to contain defeat devices. Rule 8(a) requires no more than that. In any event, the first amended complaint alleges the mileage of each vehicle, that each was screened to ensure it been properly maintained, and that each was free of potential emission-control defects.

Defendants make too much of this Court's earlier observation that the Plaintiffs' lack of corroborating evidence of a defeat device did not move their allegations "across the line from conceivable to plausible." See Twombly, 550 U.S. at 570:

Plaintiffs have not (by analogy to the plaintiffs in Mercedes I or Counts) cited independent entities that have levied defeat-device accusations against BMW for the particular engines at issue. Rather, Plaintiffs allege more generally that "[i]n Europe, watchdog groups, NGOs, and government agencies have cited virtually every manufacturer, including BMW, for violating the lower European emissions standards." There is no allegation that pinpoints any particular European governmental agency's citation of BMW with respect to its diesel cars in general, or the Subject Vehicles in particular. Rather, Plaintiffs allege (1) that a non-profit organization called Transportation and Environment accused many diesel vehicles of employing defeat devices, including certain BMW models and engines, but did not cite the Subject Vehicles at issue here; and (2) that a group called the International Council on Clean Transportation ("ICCT") released a report analyzing the real world versus lab testing emissions of many manufacturers' vehicles and found a different BMW model (not any of the Subject Vehicles) to have polluted above the European standard. Plaintiffs do not allege that these different BMW models have the same engines or use the same deceptive technology as the Subject Vehicles.

\*7 ...

The allegations here fall short of those in Mercedes. Plaintiffs have not alleged that any governmental organization has accused BMW of evading regulators with defeat devices in their diesel cars, Plaintiffs also have not alleged that the Defendants admitted any wrongdoing. These corroborating allegations were essential to the Mercedes I court's finding that the plaintiffs' testing sufficed to make the defeat device inference plausible.

Ultimately, without sufficient corroborating allegations, I am persuaded to dismiss the Complaint because the Plaintiffs have presented little beyond emissions test results for a single vehicle—one used 2012 X5.

(DE 59 at 20-21). A closer reading of that opinion reveals that I did not view independent corroborating evidence as a necessary condition that Plaintiffs needed to allege to withstand a Rule 12(b) motion. Rather, the opinion states that in the absence of adequate testing (which Plaintiffs had failed alleged in the consolidated class action complaint), such evidence *might* suffice to burnish the one-vehicle sample size enough to state a claim for relief. To be sure, Defendants have submitted a trove of news articles that emphasize the BMW was never implicated in the clean diesel scandal like many of its competitors. (See DE 68-4 through -20). However, the lack of a governmental investigation does not, by itself, demonstrate the absence of a defeat device or, by extension, deprive Plaintiffs of Article III standing.

The first amended complaint also adequately alleges an injury fairly traceable to Defendants' conduct. Plaintiffs allege that Defendants misled them by advertising and failing to disclose material information, that they were exposed to these misrepresentations or nondisclosures, that but for Defendants' conduct they would not have bought the vehicles or would have paid less for them, and that all Plaintiffs overpaid for their vehicles. Each plaintiff has also pled reliance on misrepresentations and omissions, has alleged BMW's and Bosch's conduct in that enterprise, and claimed that he or she paid an artificially high market price because of Defendants' false advertisements and conduct. Taken together, these specific allegations demonstrate that Plaintiffs' alleged injuries are fairly and directly traceable to the conduct of BMW and Bosch.

Accordingly, I find that the first amended complaint has cured the deficiencies of the consolidated class action complaint with respect to the threshold issue of Article III standing.

### C. Federal Law Claim (RICO)

Plaintiffs allege that Defendants' conduct violates the federal RICO statute. See 18 U.S.C. § 1962(c)–(d); see also 18 U.S.C. § 1964 (granting civil remedies for RICO violation). The RICO enterprise is alleged to be one by which the BMW and Bosch defendants coordinated their operations through the design, manufacture, distribution, testing process, and sale of the subject vehicles.

Section 1962(c) makes it "unlawful for any person employed by or associated with any enterprise engaged in, or the activities of which effect, interstate or foreign commerce, to conduct or participate, directly or indirectly, in the conduct of such enterprise's affairs through a pattern of racketeering activity or collection of unlawful debt." 18 U.S.C. § 1962(c)); see also In re Ins. Brokerage Antitrust Litig., 618 F.3d 300, 362-63 (3d Cir. 2010). Section 1962(d) makes it "unlawful for any person to conspire to violate any of the provisions of

subsection (a), (b), or (c) of this section." To establish a claim under section 1962(c), a plaintiff must allege (1) conduct (2) of an enterprise (3) through a pattern (4) of racketeering activity. Sedima, S.P.R.L. v. Imrex Co., 473 U.S. 479, 482–83 (1985); see also District 1199P Health & Welfare Plan v. Janssen, L.P., 784 F.Supp.2d 508, 518–19 (D.N.J. 2011) (citation omitted).

\*8 The term "enterprise" for RICO purposes is exceedingly broad. See Boyle v. United States, 556 U.S. 938, 944 (2009). It includes "any individual, partnership, corporation, association, or other legal entity, and any union or group of individuals associated in fact although not a legal entity." Ins. Brokerage, 618 F.3d at 362–63 (citing 18 U.S.C. § 1961(4)). With respect to the pattern of racketeering activity, the statute "requires at least two acts of racketeering activity within a ten-year period," which may include federal mail fraud under 18 U.S.C. § 1341 or federal wire fraud under 18 U.S.C. § 1343. Id. (citations omitted). In addition, "the plaintiff only has standing if, and can only recover to the extent that, he has been injured in his business or property by the conduct constituting the violation." Sedima, 473 U.S. at 496.

The racketeering predicate acts alleged here are mail fraud, 18 U.S.C. § 1341, and wire fraud, 18 U.S.C. § 1343. Both statutes provide that "[w]hoever, having devised a scheme or artifice to defraud ... for the purpose of executing such scheme or artifice" either (a) "places in any post office or authorized depository for mail matter, any matter or thing," or (b) "transmits or causes to be transmitted by means of wire ... in interstate or foreign commerce" virtually any sort of material shall be guilty of an offense. *See* 18 U.S.C. §§ 1341 & 1343.

In addition to the requirements described above, a successful RICO plaintiff must also demonstrate standing to bring a RICO claim in the first place. This is not the minimal jurisdictional showing of Article III standing, but a judge-made limitation. One absolute bar to RICO standing is the so-called "indirect purchaser rule." The Supreme Court developed the indirect purchaser rule in the antitrust context, when it held that Clayton Act plaintiffs may not demonstrate injury by providing evidence only of indirect purchases. *Ill. Brick Co. v. Illinois*, 431 U.S. 720, 737 (1977).

It must be acknowledged that the rule is somewhat arbitrary and policy-based; after all, if Smith is overcharged for an item and resells the item to Jones, then Jones, too, may be overcharged as a result. The *Illinois Brick* Court

warned, however, that allowing Jones or other indirect purchasers down the line to recover under such a theory would "transform treble-damages actions into massive multiparty litigations involving many levels of distribution and including large classes of ultimate consumers remote from the defendant." *Id.* at 739. Moreover, the indirect purchaser rule prevents defendants from being exposed to "multiple liability" should both indirect and direct purchasers in a distribution chain be permitted to assert claims arising out of a single overcharge. *McCarthy v. Recordex Serv., Inc.*, 80 F.3d 842, 851 (3d Cir. 1996).

Because 18 U.S.C. § 1964(c), RICO's private cause of action, was modeled on the Clayton Act, "antitrust standing principles apply equally to allegations of RICO violations." *McCarthy*, 80 F.3d at 855; *see also Holmes v. Sec. Inv'r Prot. Corp.*, 503 U.S. 258, 270–74 (1992). In *Holmes*, the Court explicitly held that federal jurisprudence interpreting antitrust principles governs RICO claims, because Congress modeled RICO's civil action provision on a substantially similar provision in the Clayton Act:

The key to better interpretation lies in some statutory history. We have repeatedly observed, *see Agency Holding Corp. v. Malley-Duff & Assocs., Inc.*, 483 U.S. 143, 150-51, 107 S.Ct. 2759, 97 L.Ed.2d 121 (1987) ... that Congress modeled § 1964(c) ... [of RICO after] the federal antitrust laws, § 4 of the Clayton Act ...

In Associated General Contractors [v. Cal. State Council of Carpenters, 459 U.S. 519 (1983)] ... we discussed how Congress enacted § 4 in 1914 with language borrowed from § 7 of the Sherman Act, passed 24 years earlier. Before 1914, lower federal courts had read § 7 to incorporate common-law principles of proximate causation ... and as we reasoned, as many lower federal courts had done before us ... that congressional use of the § 7 language in § 4 presumably carried the intention to adopt "the judicial gloss that avoided a simple literal interpretation." ... Thus, we held that a plaintiff's right to sue under § 4 required a showing that the defendant's violation not only was a "but for" cause of his injury[] but was the proximate cause as well.

\*9 The reasoning applies just as readily to § 1964(c) [of RICO]. We may fairly credit the 91st Congress, which enacted RICO, with knowing the interpretation federal courts had given the words earlier Congresses had used first in § 7 of the Sherman Act, and later in the Clayton Act's § 4.... It used the same words, and we can only assume it

intended them to have the same meaning that courts had already given them.

Holmes, 503 U.S. at 267-68.

Here, none of the subject vehicles were acquired directly from BMW (or Bosch, for that matter). (1AC ¶¶ 31–70). Instead, the Plaintiffs allege that they acquired their vehicles from a dealer, from a private party, or at auction. In fact, very few of the subject vehicles were acquired from an authorized BMW dealer at all; most seem to have been acquired on the secondary market.<sup>8</sup> The Third Circuit and courts in this District have repeatedly held that such indirect purchasers lack standing to assert RICO claims. See, e.g., McCarthy, 80 F.3d at 854 (plaintiffs were not direct purchasers of allegedly overpriced photocopies and therefore lacked antitrust and RICO standing); Minnesota by Ellison v. Sanofi-Aventis U.S. LLC, No. 18-14999, 2020 WL 2394155 at \*8-9 (D.N.J. Mar. 31, 2020) (plaintiffs lacked RICO standing because none purchased insulin directly from defendants); MSP Recovery Claims, Series, LLC v. Sanofi Aventis U.S. LLC, No. 18-2211, 2019 WL 1418129 at \*16 (D.N.J. Mar. 29, 2019) (heightened coinsurance payments and fraudulent benchmark prices of insulin did not bestow RICO standing because plaintiffs failed to allege they directly purchased insulin from defendants); In re Insulin Pricing Litig., No. 17-699, 2019 WL 643709 at (D.N.J. Feb. 15, 2019) (allegation that benchmark prices "directly" affected price paid by consumers did not overcome indirect purchaser bar to RICO standing; indirect purchaser rule applies even when alleged improper price inflation is passed along on a "dollar for dollar basis"). Under the law within this Circuit, then, Plaintiffs do not have standing to pursue their RICO claims against BMW and Bosch, because each plaintiff is an indirect purchaser of his or her vehicle.

- Perhaps more appropriately stated, the vast majority of the subject vehicles were acquired on the *tertiary* market, because, for RICO purposes, car dealerships themselves are already considered a secondary market.
- Practically speaking, of course, applying the indirect purchaser rule to car buyers forecloses all consumer RICO claims against car manufacturers, because state laws generally prohibit manufacturers' direct sales of automobiles. A RICO remedy would thus seem to be confined to car dealers, and there are no dealers (at least qua dealers) among the plaintiff class. So far as our research has disclosed, there is no automobile exception to the indirect purchaser rule.

In response, Plaintiffs argue that Defendants are attempting "to graft a privity requirement into RICO by means of an indirect purchaser theory," (DE 73 at 8), and that both *Bridge v. Phoenix Bond & Indem. Co.*, 553 U.S. 639 (2008), and *In re Avandia Mktg., Sales Practices & Prod. Liab. Litig.*, 804 F.3d 633 (3d Cir. 2015), carved out exceptions to the indirect purchaser rule in RICO cases. (DE 73 at 8–10).

First, there is no question of "grafting" anything. The Third Circuit has clearly and directly held that "only the purchaser immediately downstream from the alleged [RICO violator]" possesses standing to pursue an action. *McCarthy*, 80 F.3d at 848. If this be privity, make the most of it.

\*10 Second, Plaintiffs' reliance on *Bridge* and *Avandia* conflates the standing and causation issues under RICO. Those are distinct issues which require discrete analyses. Thus, Plaintiffs' claim would still fail for lack of RICO standing even if *Bridge* and *Avandia* controlled the issue of causation.

Bridge at least addresses standing, but it does not undercut the indirect purchaser rule as it applies to Plaintiffs' RICO claims. In *Bridge*, the Court held that a plaintiff who is injured "by reason of" a pattern of mail fraud may have RICO standing "even if he [or she] has not relied on any misrepresentations." 553 U.S. at 649–50. The *Bridge* plaintiff, however, was not an indirect purchaser; the case does not support any argument for RICO standing on behalf of plaintiffs multiple levels down the consumer chain.

In *Avandia*, the Third Circuit explained that "if there is a sufficiently direct relationship between the defendant's wrongful conduct and the plaintiffs' injury, ... a RICO plaintiff who did not directly rely on a defendant's misrepresentation can still establish *proximate causation*." (DE 73 at 9 (quoting 804 F.3d at 643) (emphasis added)). Apart from the fact that *Avandia* speaks to reliance and causation, not standing, the case presents numerous factual differences. The *Avandia* plaintiffs were third-party payors who included the drug Avandia in their formulary decisions at favorable rates, relying on material misrepresentations made by the defendant manufacturer. *Avandia*, 804 F.3d at 636. By contrast, Plaintiffs here allege that their damages stem from inflated prices paid by car dealers and original owners before Plaintiffs purchased the vehicles from those intermediaries.

Critically, the *Avandia* plaintiffs did not seek a remedy for payments made to third parties based on misrepresentations

made by a manufacturer. Instead, the claim there concerned the defendants' failure to disclose known health risks of various drugs ultimately included in their formularies:

The conduct that allegedly caused plaintiffs' injuries is the same conduct forming the basis of the RICO scheme alleged in the complaint—the misrepresentation of the heart-related risks of taking Avandia that caused [third-party payors] and [pharmacy benefit managers] to place Avandia in the formulary. The injury alleged by the [third-party payors] is an economic injury independent of any physical injury suffered by Avandia users. And, as far as we can tell, prescribing physicians did not suffer RICO injury from [the] marketing of Avandia.

*Avandia*, 804 F.3d at 644 (emphasis added). *Avandia* suggests by analogy, that if there was a RICO injury in our case, it was the car dealer—not any Plaintiff—who suffered it.

Each Plaintiff here is an indirect purchaser and therefore lacks standing to maintain a RICO claim against Defendants. Accordingly, Plaintiffs' RICO claim (Count 1) is **DISMISSED**.

### **D. State Law Claims**

Plaintiffs also bring common-law and statutory claims under the laws of various states. Counts 2 through 53 allege fraudulent concealment and violations of the consumerprotection laws of the twenty-four states in which at least one named plaintiff resides. Counts 54 through 79 concern the statutory consumer-protection laws of the remaining twentysix states.

Plaintiffs' common-law claims proceed on a fraudulent-concealment theory:

\*11 BMW understood that a consumer deciding between a gas BMW and a diesel BMW had to have a reason to pay more for a diesel. For this reason BMW made numerous statements about lower emissions, the environment, and fuel economy that omitted material. BMW made these statements because it understood that information about lower emissions, fuel economy, and performance were material to potential consumers of diesel vehicles. The misrepresentations and omissions common to all state law claims can be summarized as follows:

The vehicles "met emissions standards in all states." [false];

"BMW Efficient Dynamics Means Less Emissions"; [false and misleading];

Its engines "protect the environment every day." [misleading];

Its engines turned nitric oxides "into environmentally friendly compatible nitrogen and water vapor." [false and misleading];

Its engines offered "increased power with decreased fuel consumption and emissions." [misleading as in many circumstances with emissions manipulation there is no decrease in emissions.];

BMW claimed its SCR catalyst ensured effective reduction of NOx, in part by urea dosing (¶ 123) [false as SCR efficiency was manipulated to allow increased emissions];

BMW claimed its polluting vehicles generated "less emissions" [misleading as this is true only in certain circumstances and emissions are not less than a comparable BMW gas model].

"Exemplary fuel economy" [false and misleading as fuel economy is decreased during active regeneration, and any fuel economy advantage only occurs when the emissions system is manipulated].

"Consistent distribution of AdBlue ... is ensured by the SCR mixer [false as the SCR mixer is programmed to reduce admissions control].

 $(1AC \, \P \, 400).$ 

Plaintiffs allege that both BMW and Bosch were required to disclose concealed facts:

(1) [T]hey each made or were complicit in statements that were misleading for failure to disclose material facts; (2) Defendants knew the omitted facts were material to consumers which is why they made or were complicit in statements made about emissions, the environment and fuel economy; (3) Defendants were in a superior position and had exclusive knowledge of the true facts; and (4) these omissions related to the core function of a diesel vehicle. As to exclusive knowledge defendants had contractual agreements requiring strict confidentiality as to the software programming used to manipulate emissions performance.

 $(1AC \, \P \, 401).$ 

Defendants argue that this Court should dismiss Plaintiffs' consumer-protection and fraudulent-concealment claims. BMW and Bosch claim that Plaintiffs have failed plead facts showing (1) standing to bring claims in states in which they do not reside (DE 68-1 at 42–43; DE 69-1 at 19); and (2) the requirements of Rule 9(b) (DE 68-1 at 45–47; DE 69-1 at 19). Bosch also alleges that Plaintiffs have not properly alleged a duty to disclose. (DE 69-1 at 19–21).

# 1. State-Law Standing Issues

Essentially, Defendants' first argument is that Counts 54-79—the claims relating to the consumer-protection statutes of the states in which no named plaintiff resides—should be dismissed because the named plaintiffs, as nonresidents of those states, lack standing to bring those claims. A more prudent approach would be to defer consideration of this argument until the certification stage. To the extent the proposed class is not certified, or is limited, many of these issues might be rendered moot. I here follow the lead of other cases that have declined to address similar issues in advance of class certification. See, e.g., Sheet Metal Workers Nat. Health Fund v. Amgen Inc., No. 07-5295, 2008 WL 3833577 at \*9 (D.N.J. Aug.13, 2008) (declining to address argument that plaintiff lacks standing to bring claims under laws of states in which plaintiff failed to allege an injury and explaining that "because class certification creates the jurisdictional issue, the Court must treat the statutory standing issue before it deals with Article III standing, as instructed by Ortiz") (citing Ortiz v. Fibreboard Corp., 527 U.S. 815 (1999)); In Re Hypodermic Prods. Antitrust Litig., No. 05-1602, 2007 WL 1959225 at \*15 (D.N.J. June 29, 2007) (deferring consideration of argument that "Plaintiffs do not enjoy standing to raise state antitrust claims in jurisdictions in which they do not reside" until after class certification issues have been resolved); Clark v. McDonald's Corp., 213 F.R.D. 198, 204 (D.N.J.2003) (considering it appropriate to decide class certification before resolving Article III standing challenges where defendant had argued that "Clark does not enjoy standing to assert claims on behalf of class members regarding restaurants that Clark has not visited, or in states Clark has not visited").

# 2. Fraudulent Concealment and Rule 9(b)

\*12 Defendants also seek dismissal of the common-law claims. The parties are less than specific about which states' common law applies, and do not point to any relevant distinctions between the laws of those states. I therefore default to the New Jersey law of fraudulent concealment, which has five essential elements: (1) a material misrepresentation or omission of a presently existing or past fact; (2) knowledge or belief by the defendant of its falsity or knowing the omission to be material; (3) intention that the other person rely on it; (4) reasonable reliance thereon by the other person; and (5) resulting damages. *Gennari v. Weichert Co. Realtors*, 148 N.J. 582, 610 (1997); *Delaney v. Am. Express Co.*, No. 06-5134, 2007 WL 1420766 at \*5 (D.N.J. May 11, 2007).

Rule 9(b)'s specificity requirement applies to fraudulent concealment claims. *GKE Enters.*, *LLC v. Ford Motor Credit Co. LLC USA*, No. 09-4656, 2010 WL 2179094 at \*4 (D.N.J. May 26, 2010). Fraud-by-omission claims, however, are by their nature less susceptible of precise formulation than affirmative misrepresentation claims. <sup>10</sup> *See Feldman v. Mercedes Benz USA*, No. 11-984, 2012 WL 6596830 at \*10 (D.N.J. Dec. 18, 2012). A fraud-by-omission claim is sufficient so long as it places "the defendant on notice of the precise misconduct with which it is charged," *Montich v. Miele USA, Inc.*, 849 F. Supp. 2d 439, 443 (D.N.J. 2012) (quoting *Frederico v. Home Depot*, 507 F.3d 188, 200 (3d Cir. 2007)).

We need not tarry over the paradoxes inherent in a requirement of stating the precise time, place, location, and manner in which something did not occur.

BMW<sup>11</sup> contends that Plaintiffs have failed to specify the who, what, when, where, and how of the allegedly fraudulent scheme, as required by Rule 9(b). (DE 68-1 at 46). Here, however, BMW mistakenly focuses on the alleged affirmative misrepresentations to the exclusion of the claimed omissions. For example, BMW argues that "[r]ather than allege conduct specifically and separately as to each BMW entity, the FAC refers to supposed misrepresentations and omissions by 'BMW' or the 'Defendants,' which is insufficient under Rule 9(b)" and that "the FAC fails to identify with specificity the statements on which named Plaintiffs relied, when those statements were made, or who made them." (DE 68-1 at 46). BMW's argument asks too much of Rule 9(b), which imposes a less specific pleading standard on fraudulent omissions than it does on affirmatively fraudulent statements. The "who, what, when, where and how" is not so strictly required

here, because Plaintiffs cite BMW's affirmative statements primarily to establish the context for what BMW should *also* have said to ensure that those statements did not mislead. Moreover, the first amended complaint does not engage in impermissible group pleading, because it distinctly pleads the roles that that BMW and Bosch allegedly played in carrying out the scheme. Plaintiffs cite numerous specific examples of how each defendant furthered the allegedly fraudulent conduct. (1AC  $\P$  379).

Bosch fully adopts BMW's argument on this point. (DE 69-1 at 19).

Plaintiffs' allegations of misrepresentations, and particularly those involving omissions, have sufficiently notified BMW and Bosch of the precise misconduct with which they are charged: "Each Plaintiff alleges exposure to the materially deficient messaging because each 'selected and ultimately purchased [his or her vehicle], in part, because of the diesel system, as represented through advertisements and representations made by BMW,' including 'advertisements on BMW's website and representations from the dealership touting the efficiency, fuel economy, and power and performance of the engine.'" (DE 73 at 45–46).

\*13 Moreover, Plaintiffs allege that Defendants designed the defeat device to provide the perception of reduced emissions while avoiding the cost of reduced emissions. These allegations are sufficient to permit an inference fraudulent intent, and they meet the specificity requirements of Rule 9(b). Similar allegations have been found in other automotive-defect cases, both within and without this district, to satisfy Rule 9(b). See Counts v. Gen. Motors, LLC, 237 F. Supp. 3d 572, 599 (E.D. Mich. 2017) (plaintiffs sufficiently alleged that GM "actively concealed and had exclusive knowledge of the alleged 'defeat device' "); In re Volkswagen "Clean Diesel" Mktg., Sales Practices, & Prod. Liab. Litig., 349 F. Supp. 3d 881, 915 (N.D. Cal. 2018) (finding that fraudulent omissions claims survived, because plaintiffs identified "the specifics of what VW failed to disclose: (1) that 'the Clean Diesel engine systems were not EPA-compliant,' and (2) that the class vehicles 'used software that caused the vehicles to operate in low-emission test mode during emissions testing' "); Feldman, 2012 WL 6596830 at \*10 (holding that plaintiffs adequately stated a claim of fraud by omission where they "allege[d] specific facts showing Defendants' knowledge and concealment of the alleged defect").

This Court will not dismiss Plaintiffs' state-law fraudulent-concealment claims for failure to meet the standards of Rule 9(b).

# 3. Bosch's Duty to Disclose

Concerning Bosch, Plaintiffs' allegations of fraudulent concealment rest on a theory of fraud by omission. (1AC ¶¶ 414–15). Under New Jersey law, "courts will not imply a duty to disclose, unless such disclosure is necessary to make a previous statement true or the parties share a 'special relationship.' "Lightning Lube, Inc. v. Witco Corp., 4 F.3d 1153, 1185 (3d Cir. 1993). The categories of relationships that give rise to a duty to disclose are: "(1) fiduciary relationships, such as principal and agent, client and attorney, or beneficiary and trustee; (2) relationships where one party expressly reposes trust in another party, or else from the circumstances, such trust necessarily is implied; and (3) relationships involving transactions so intrinsically fiduciary that a degree of trust and confidence is required to protect the parties." Id.

Plaintiffs also draw attention to a similar case which held that where an omission makes the representation misleading—that is, where "Plaintiffs allege active concealment of the truth"—then Plaintiffs "need not establish a duty to disclose." (DE 72 at 7 n.12):

Defendants contend that a number of states—namely, Massachusetts, Maryland, Maine, New Jersey, Nevada, Oregon, Pennsylvania, South Carolina, and Tennessee—recognize a fraudulent concealment claim only where there is a fiduciary relationship between the plaintiff and defendant. *See* FCA/VM Mot. at 54. Defendants are incorrect. Although Defendants do cite some authority to support their position,

[T]here is substantial authority [that] a fiduciary relationship is not the only time a duty to disclose arises; also, an affirmative act of concealment by the defendant effectively negates the duty-to-disclose requirement (*i.e.*, there is a difference between silence, where a duty to disclose is required, and active concealment, where there is no such requirement). In this regard, Plaintiffs do not claim that Defendants were simply silent but rather that they took affirmative steps to conceal the defeat devices—including not identifying them for the EPA and CARB.... A duty to disclose thus may obtain in a variety of circumstances or indeed, may not even be required in some situations[.]

...

See U. Jersey Bank v. Kensey, 306 N.J. Super. 540, 704 A.2d 38, 45 (1997) (indicating agreement with Restatement (Second) of Torts that there is a duty "to disclose to another 'facts basic to the transaction, if he knows that the other is about to enter into it under a mistake ... and that the other, because of the relationship between them, the customs of the trade or other objective circumstances, would reasonably expect a disclosure of those facts'").

\*14 In re Chrysler-Dodge-Jeep Ecodiesel Mktg., Sales Practices, & Prod. Liab. Litig., 295 F. Supp. 3d 927, 1009 (N.D. Cal. 2018).

Here, Plaintiffs do not assert that they fall into one of the special relationship categories with Bosch. The focus of the inquiry is only whether a duty to disclose existed to prevent a previous statement from being misleading.

Bosch claims that "Plaintiffs fail to allege facts to show that Bosch LLC owed a duty of disclosure to Plaintiffs," (DE 69-1 at 19-20), and that "[a]s far as Plaintiffs were concerned, Bosch LLC was 'a complete stranger' that 'dealt with [Plaintiffs] only through impersonal [and indirect] market transactions.' " (DE 69-1 at 21 (quoting Chiarella v. United States, 445 U.S. 222, 232-33 (1980)). Nevertheless, Plaintiffs' allegations here suffice to show that Bosch had a duty to Plaintiffs to disclose the falsity of its statements. Bosch is alleged to have knowingly participated in designing the fraudulent emissions system (1AC ¶¶ 268–78); developed coded language about the defeat device and concealing the defeat device (1AC ¶¶ 279–80); and actively and knowingly deceived U.S. regulators about its diesel technology for the benefit of all affected vehicles (1AC ¶¶ 281-83). These allegations are sufficient to establish an obligation by Bosch to correct the record. See In re Volkswagen Timing Chain Prod. Liab. Litig., No. 16-2765, 2017 WL 1902160 at \*20 (D.N.J. May 8, 2017) (finding that the plaintiffs pled a partial disclosure after which the defendant had a duty to disclose "any and all information regarding the Timing Chain System" to plaintiffs, where the plaintiffs alleged that the defendant "represent[ed] in the maintenance schedules that the timing belt, which performs the same function as the Timing Chain System, will need service after a certain time but makes no representation that the Timing Chain System will need maintenance"); Strawn v. Canuso, 271 N.J. Super. 88, 104 (App. Div. 1994) (establishing a duty on buyers and brokers of real estate to disclose the existence of off-site conditions that were unknown to the buyer but that were known or should have been known to the seller and that would reasonably and foreseeably affect the value or desirability of the property), *aff'd*, 140 N.J. 43 (1995).

In Strawn, the New Jersey Supreme Court adopted the Restatement (Second) of Torts which imposes a "duty upon a party to disclose to another 'facts basic to the transaction, if he knows that the other is about to enter into it under a mistake ... and the other, because of the relationship between them, the customs of the trade[,] or other objective circumstances, would reasonably expect a disclosure of those facts," "where the nondisclosure of those facts amounts to taking advantage of a plaintiff's ignorance, such that it would be "shocking to the ethical sense of the community, and [would be] so extreme and unfair, as to amount to a form of swindling." "U. Jersey Bank, 306 N.J. Super. at 554 (citations omitted). Bosch's active concealment of the existence of the defeat device amounts to such a situation. Cf. Chrysler-Dodge-Jeep, 295 F. Supp. 3d at 1009 (finding that allegations of defendants' active concealment of the defeat devices was sufficient to establish a duty to disclose under); Counts, 237 F. Supp. 3d at 600 (noting that defendant's alleged active concealment of the defeat device was sufficient to establish a duty to disclose). Accordingly, Plaintiffs' claims of fraudulent concealment by Bosch will not be dismissed on this basis.

# 4. Statutory Consumer-Fraud Issues

# i. New Jersey's Consumer Fraud Act (Count 32)

\*15 Defendants allege that the New Jersey Consumer Fraud Act requires plaintiffs to plead "ascertainable loss." That element, Defendants say, "require[s] plaintiffs to specify the price paid for the product and the price of comparable products to adequately state a claim." (DE 68-1 at 48 (quoting *In re Riddell Concussion Reduction Litig.*, 77 F. Supp. 3d 422, 439 (D.N.J. 2015)); see also N.J. Stat. Ann. § 56:8-2).

Defendants are correct that a claim under the New Jersey Consumer Fraud Act requires an allegation of ascertainable loss. *See Riddell*, 77 F. Supp. 3d at 436–37. The plaintiff need not, however, plead ascertainable loss with pinpoint specificity. *See Maniscalco v. Brother Int'l Corp. (USA)*, 627 F.Supp.2d 494, 503 (D.N.J.2009) (citing *Perkins v. DaimlerChrysler Corp.*, 383 N.J. Super. 99, 111 (App. Div. 2006)) ("Here, plaintiff alleged in her complaint that she suffered an ascertainable loss. She did not allege the nature

of that loss, nor was she so required at that stage. Defendant's motion to dismiss, unlike the summary judgment procedure, did not require, in order to avoid dismissal, that the plaintiff provide evidential material to rebut defendant's contention that she had not sustained ascertainable loss ...."); Lamont v. OPTA Corp., 2006 WL 1669019 (N.J. Super. Ct. App. Div. 2006) ("There is nothing ... that requires the pleading of an ascertainable loss element of a Consumer Fraud Act cause of action with any special specificity ...."). Even in opposition to a motion for summary judgment, "[a]n estimate of damages, calculated within a reasonable degree of certainty will suffice to demonstrate an ascertainable loss." Thiedemann v. Mercedes-Benz USA, LLC, 183 N.J. 234, 249 (2005) (internal quotation and citation omitted). At the motion to dismiss stage, alleging a diminution in value due to the defect is sufficient. Maniscalco, 627 F.Supp.2d at 503 (finding that conclusory statement about the replacement cost of a defective machine was an adequate allegation of ascertainable loss); Strzakowlski v. GMC, No. 04-4740, 2005 WL 2001912 at \*6-7 (D.N.J. Aug. 16, 2005) (alleging diminution in value satisfies the CFA's loss requirement); cf. Perkins, 383 N.J. Super. at 110-11

Here, each New Jersey plaintiff alleges the actual price paid for the car and the amount of the price premium allegedly attributable to the fraud. The first amended complaint also alleges that these calculations are "based on analysis of other emissions cases." (1AC ¶ 319). The plaintiff need not adduce his evidence at this, the pleading stage. These allegations satisfy the ascertainable loss element of the New Jersey Consumer Fraud Act.

#### ii. Mississippi's Consumer Protection Act (Count 28)

Defendants argue that the Mississippi Consumer Protection Act claim must be dismissed for failure to comply with Mississippi's requirement of participation in settlement programs before filing suit. See Miss. Code Ann. § 75-24-15(2).12

12 Defendants do not address—apart from the arguments that have already been discussed, *supra*—the sufficiency of the factual allegations.

The legal question boils down to one of federalism. A matter may proceed as a federal class action, regardless of a state procedural bar, so long as the application of Rule 23 does not "abridge, enlarge or modify any substantive right." *Shady*  Grove Orthopedic Assocs., P.A. v. Allstate Ins. Co., 559 U.S. 393, 407 (2010) (quoting Rules Enabling Act, 28 U.S.C. § 2072(b)). Courts applying Shady Grove have gone so far as to hold that a federal class action may proceed on state-law claims despite state statutes prohibiting class action treatment. See, e.g., In re Hydroxycut Marketing and Sales Practices Litig., 299 F.R.D. 648 (S.D. Cal. 2014) (permitting claims under state consumer-protection statutes to proceed as class action under Rule 23 even where state statutes do not allow class actions); see also Lisk v. Lumber One Wood Preserving, LLC, 792 1331 (11th Cir. 2015) (same application).

\*16 Under the Supreme Court's decision in Shady Grove, state rules, even if procedural in form, may control in federal court when they are "part of a State's framework of substantive rights or remedies." 559 U.S. at 419 (Stevens, J., concurring). There is no consensus among the federal cases as to whether pre-suit notice or settlement requirements are "substantive" or "procedural." Some have applied such provisions, reasoning that failure to do so "would encourage forum shopping and the inequitable administration of laws." In re Effexor Antitrust Litig., 357 F. Supp. 3d 363, 387-88 (D.N.J. 2018) (quoting In re Asacol Antitrust Litig., No. 15-12730, 2016 WL 4083333 at \*15 (D. Mass. July 20, 2016)); see also In re Insulin Pricing Litigation, No. 17-699, 2020 WL 831552 at 9 (D.N.J Feb. 20, 2020) (dismissing claim for failure to comply with Mississippi's pre-suit dispute resolution requirement); In re Lipitor Antitrust Litigation, 336 F.Supp.3d 395, 415-17 (D.N.J. 2018) ("In sum, the Court finds that the ... notice provisions ... are applicable here and Plaintiffs failed to comply."); In re Chocolate Confectionary Antitrust Litig., 749 F.Supp.2d 224, 232 (M.D. Pa. 2010) (finding failure to comply with Hawaii notice requirement "warrants dismissal"). Others have treated such provisions as procedural, i.e., not sufficiently a part of the relevant states' framework of substantive rights or remedies to be controlling. See In re Restasis (Cyclosporine Ophthalmic Emulsion) Antitrust Litig., 355 F.Supp.3d 145, 156 (E.D.N.Y. 2018) ("Hawaii's law regulates only when private plaintiffs can litigate the case. It does not alter the substantive elements of plaintiffs' claims."); In re Propranolol, 249 F.Supp.3d at 728 n.24 (dismissal not required for failure to comply with Hawaii's procedural notice rule); In re Broiler Chicken Antitrust Litig., 290 F.Supp.3d 772, 817 (N.D. Ill. 2017) (declining to dismiss Arizona antitrust claim notwithstanding late notice to attorney general); In re Aggrenox Antitrust Litig., 94 F.Supp.3d 224, 254 (D. Conn. 2015) (declining to dismiss based on the plaintiffs' failure to plead compliance with the notice requirements of the Hawaii antitrust statute);

In re Aftermarket Filters Antitrust Litig., No. 08-4883, 2009 WL 3754041 at \*6 (N.D. Ill. Nov. 5, 2009) (finding Hawaii antitrust "statute does not provide for dismissal of the action for failure to comply [with the pre-suit notice requirement], and that dismissal is inconsistent with the remedial purposes of the statute").

Whether Rule 23 would abridge a substantive right, however, is an issue that need not be faced until the certification stage. The elements of a cause of action are set forth. The motion to dismiss the Mississippi claim is, at least for now, denied.

# iii. Alaska's Unfair Trade Practices and Consumer Protection Act (Count 54)

The first amended complaint pleads violations of the Alaska Unfair Trade Practices and Consumer Protection Act, Alaska Stat. Ann. § 45.50.471 et seq., "for notice purposes only." (1AC ¶ 1181). Defendants argue that because the complaint does not identify an Alaska plaintiff, the putative class does not have standing to bring this claim. (DE 68-1 at 49). Defendants have a point, but for the reasons discussed supra, the issue of standing to bring claims on behalf of unnamed plaintiffs, some of them potentially from Alaska, is more appropriately resolved at the certification stage.

# iv. West Virginia's Consumer Credit and Protection Act (Count 78)

Likewise, the first amended complaint pleads violations of the West Virginia Consumer Credit and Protection Act, W. Va. Code § 46A-1-101 *et seq.*, "for notice purposes only." (1AC ¶ 1379). Again, I will defer consideration until the certification stage.

# v. Iowa's Private Right of Action for Consumer Frauds Act (Count 61)

Defendants argue that the Iowa Private Right of Action for Consumer Frauds Act, Iowa Code § 714H.1 et seq., requires that class actions under that act secure pre-clearance from the attorney general. (DE 68-1 at 50). Plaintiffs have not alleged such preclearance. Whether Rule 23 would abridge a substantive right, see Shady Grove, 559 U.S. at 407, is an issue that need not be faced until the certification stage. At least for now, the motion to dismiss the Iowa claim is denied.

# vi. Georgia's Uniform Deceptive Trade Practices Act (Count 13)

The Georgia Uniform Deceptive Trade Practices Act does not authorize private damages lawsuits. *See* Ga. Code Ann. § 10-1-373. This lawsuit, however, is about injunctive relief at least as much as it is about damages. The first amended complaint sufficiently alleges that, for Rule 12(b) (6) purposes, the subject vehicles need to be fixed and that Plaintiffs' injuries can be redressed, at least in part, by a recall or a replacement. The motion to dismiss the Georgia UDTPA claim is therefore denied.

# vii. Minnesota's Deceptive Trade Practices Act (Count 26)

\*17 Similarly, the Minnesota Deceptive Trade Practices Act does not permit private damages lawsuits. *See* Minn. Stat. Ann. § 325d.45. The motion to dismiss the Minnesota DTPA claim is denied. *See* subsection vi, immediately preceding.

# viii. Kentucky's Consumer Protection Act (Count 19)

Defendants point out that the Kentucky Consumer Protection Act, contains a privity requirement. *See* Ky. Rev. Stat. Ann. § 367.220(1). However, courts applying this statute have recognized an exception to the privity requirement when breach of an express warranty is alleged:

To maintain a private action under Kentucky's Consumer Protection Act, a plaintiff must generally be in privity of contract with the defendant. *Naiser* [v. *Unilever U.S., Inc.*], 975 F.Supp.2d [727,] 743 [ (2013) ] (citing *Ky. Laborers Dist. Council Health & Welfare Trust Fund v. Hill & Knowlton, Inc.*, 24 F.Supp.2d 755, 772–73 (W.D.Ky.1998) (noting that the KCPA "requires that privity of contract exist between the parties[]")). The statute typically cited for the KCPA's privity requirement states:

Action for recovery of money or property; when action may be brought—(1) Any person who purchases or leases goods or services primarily for personal, family or household purposes and thereby suffers any ascertainable loss of money or property .. may bring an action ....

K.R.S. § 367.220(1). Kentucky courts have held that this language "plainly contemplates an action by a purchaser against his immediate seller." *Skilcraft Sheetmetal, Inc. v. Ky. Mach., Inc.*, 836 S.W.2d 907, 909 (Ky. App. 1992). *As noted in Naiser, however, there is an exception to the privity requirement when express representations are alleged.* 

• • •

According to the Court in *Naiser*, since the plaintiffs had sufficiently alleged that the manufacturer made valid express warranties for Plaintiffs' benefit, ... [t]he plaintiffs were permitted to maintain a KCPA claim despite the absence of a direct buyer-seller relationship.

Bosch v. Bayer Healthcare Pharm., Inc., 13 F. Supp. 3d 730, 750 (W.D. Ky. 2014) (emphasis added); see also Skilcraft, 836 S.W.2d at 909 (a subsequent purchaser could not "maintain an action against a seller with whom he did not deal or who made no warranty for the benefit of the subsequent purchaser") (emphasis added).

Here, Plaintiffs have alleged that Defendants made an express warranty with regard to the subject vehicles. That allegation is sufficient to overcome the privity requirement, and the motion to dismiss the Kentucky CPA claim is denied.

#### III. CONCLUSION

For the foregoing reasons, the motions of BMW USA (DE 68) and Robert Bosch LLC (DE 69) are **GRANTED** in part and **DENIED** in part. Count 1 of the first amended complaint (1AC) is **DISMISSED**. The dismissal is with prejudice because it appears that further amendment would be futile.

A separate order will issue.

#### **All Citations**

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# **Tab 26**

2020 WL 8175597 Only the Westlaw citation is currently available. United States District Court, C.D. California.

Enma SAGASTUME, individually and on behalf of other members of the general public similarly situated, Plaintiff,

v.

PSYCHEMEDICS CORPORATION, et al., Defendants.

CV 20-6624 DSF (GJSx) | Signed 11/30/2020

# **Attorneys and Law Firms**

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Order GRANTING in Part and DENYING in Part Defendant Psychemedics Corporation's Motion to Dismiss and/or Strike (Dkt. 32)

Dale S. Fischer, United States District Judge

\*1 Defendant Psychemedics Corporation moves to dismiss and/or strike<sup>1</sup> Plaintiff Enma Sagastume's first amended complaint in its entirety. Dkt. 32 (Mot.). Sagastume opposes. Dkt. 33 (Opp'n). The Court deems this matter appropriate for decision without oral argument. See Fed. R. Civ. P. 78; Local Rule 7-15. For the reasons stated below, the motion is GRANTED in part and DENIED in part.

A district court "may strike from a pleading an insufficient defense or any redundant, immaterial, impertinent, or scandalous matter." Fed. R. Civ. P. 12(f). "Rule 12(f) does not authorize district courts to strike claims for damages on the ground that such claims are precluded as a matter of law." Whittlestone, Inc. v. Handi-Craft Co., 618 F.3d 970, 974-75 (9th Cir. 2010). Psychemedics does not identify material that is "redundant, immaterial, impertinent, or scandalous" in

its motion and instead identifies why the pleadings are inadequate as a matter of law. Therefore, the Court considers Psychemedic's motion as only a motion to dismiss.

#### I. BACKGROUND

Sagastume worked as an hourly-paid Accessioner/Weigher for Psychemedics from approximately May 2016 to November 2017. Dkt. 30 (FAC) ¶ 19. She brings this action on behalf of a proposed class of "[a]ll current and former hourly-paid or non-exempt employees who worked for any of the Defendants within the State of California at any time during the period from June 8, 2016 to final judgment." Id. ¶¶ 13-14.

Sagastume alleges Psychemedics failed to compensate her for job duties performed before or after her scheduled shifts and during meal periods including "performing data entry, analyzing hair samples, weighing hair samples, cleaning and organizing work station, gathering supplies necessary for work-related tasks, and receiving and answering work-related questions from supervisors and managers." Id. ¶ 27. Sagastume claims Psychemedics failed to provide her required rest and meal periods, id. ¶ 28; pay her minimum wage for all hours worked, id. ¶ 33; pay all wages due upon discharge or resignation, id. ¶ 34; complete accurate wage statements and payroll records, id. ¶¶ 36-37; reimburse for necessary business-related expenses, id. ¶ 38; and pay overtime wages, id. ¶ 40.

# II. LEGAL STANDARD

Rule 12(b)(6) allows an attack on the pleadings for failure to state a claim on which relief can be granted. "[W]hen ruling on a defendant's motion to dismiss, a judge must accept as true all of the factual allegations contained in the complaint." Erickson v. Pardus, 551 U.S. 89, 94 (2007) (per curiam). However, a court is "not bound to accept as true a legal conclusion couched as a factual allegation." Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009) (quoting Bell Atl. Corp. v. Twombly, 550 U.S. 544, 555 (2007)). "Nor does a complaint suffice if it tenders 'naked assertion[s]' devoid of 'further factual enhancement.' " Id. (alteration in original) (quoting Twombly, 550 U.S. at 557). A complaint must "state a claim to relief that is plausible on its face." Twombly, 550 U.S. at 570. This means that the complaint must plead "factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." Iqbal,

556 U.S. at 678. There must be "sufficient allegations of underlying facts to give fair notice and to enable the opposing party to defend itself effectively ... and factual allegations that are taken as true must plausibly suggest an entitlement to relief, such that it is not unfair to require the opposing party to be subjected to the expense of discovery and continued litigation." Starr v. Baca, 652 F.3d 1202, 1216 (9th Cir. 2011).

\*2 Ruling on a motion to dismiss will be "a context-specific task that requires the reviewing court to draw on its judicial experience and common sense. But where the well-pleaded facts do not permit the court to infer more than the mere possibility of misconduct, the complaint has alleged – but it has not 'show[n]' – 'that the pleader is entitled to relief.' " Iqbal, 556 U.S. at 679 (alteration in original) (citation omitted) (quoting Fed. R. Civ. P. 8(a)(2)).

As a general rule, leave to amend a complaint that has been dismissed should be freely granted. Fed. R. Civ. P. 15(a).

#### III. DISCUSSION

# A. The Landers Standard

Much of the parties' argument centers on the meaning and application of the pleading standard set out in <u>Landers v. Quality Communications</u>, <u>Inc.</u>, 771 F.3d 638 (9th Cir. 2014). Psychemedics adopts a strict interpretation of that standard and argues Sagastume failed to satisfy it. Because Sagastume disputes the accuracy of Psychemedics' understanding of Landers, the Court first examines the standard.

Landers established the pleading standard for plaintiffs bringing overtime and minimum wage claims under the Fair Labor Standards Act (FLSA), id. at 644-45, and lower courts have held Landers' reasoning applies to violations of California's minimum wage and overtime laws as well, Haralson v. United Airlines, Inc., 224 F. Supp. 3d 928, 942 (N.D. Cal. 2016); Tan v. GrubHub, Inc., 171 F. Supp. 3d 998, 1006 (N.D. Cal. 2016). Landers held "a plaintiff asserting a violation of the FLSA overtime provisions must allege that she worked more than forty hours in a given workweek without being compensated for the hours worked in excess of forty during that week." 771 F.3d at 645. The circuit affirmed the district court's dismissal of the plaintiff's claim because he "failed to provide sufficient detail about the length and frequency of [his] unpaid work to support a reasonable inference that [he] worked more than forty hours in a given week." <u>Id.</u> at 646 (alterations in original) (internal quotations omitted).

Psychemedics argues Landers stands for the proposition that plaintiffs must "specify at least a given week" in which Sagastume was deprived of overtime pay, a meal break, or a rest break. Mot. at 12. Sagastume, on the other hand, argues Landers does not require plaintiffs to "allege a specific calendar week or instance of denied overtime wages." Opp'n at 10 (internal quotation marks omitted). Each side points to several district court decisions that interpret Landers in its favor. Given the inconsistency of post-Landers California district court opinions, there is support for both positions. Some district courts have held a plaintiff need not plead facts showing a specific, particular workweek where he worked more than forty hours and did not receive overtime pay. See Varsam v. Lab. Corp. of Am., 120 F. Supp. 3d 1173, 1178 (S.D. Cal. 2015); Tan, 171 F. Supp. 3d at 1008; Slack v. Int'l Union of Operating Eng'rs, 83 F. Supp. 3d 890, 900 (N.D. Cal. 2015). Others have held Landers requires exactly that. See Perez v. Wells Fargo & Co., 75 F. Supp. 3d 1184, 1190-91 (N.D. Cal. 2014) Haralson, 224 F. Supp. at 942; Shann v. Durham Sch. Servs., L.P., 182 F. Supp. 3d 1044, 1047 (C.D. Cal. 2016).

The Court is aware of only one Ninth Circuit opinion, albeit unpublished, that meaningfully addresses the Landers standard: Boon v. Canon Business Solutions, Inc., 592 F. App'x 631 (9th Cir. 2015). The Boon court reversed a district court's ruling that a plaintiff's "complaint must contain an estimate of how much uncompensated time was worked, how often, and at what rate to survive a motion to dismiss." Id. at 632 (internal quotation marks and brackets omitted). Boon interpreted Landers to mean that "detailed factual allegations regarding the number of overtime hours worked are not required to state a plausible claim." Id. (quoting Landers, 771 F.3d at 644). Boon explained that "plaintiffs in these types of cases must allege facts demonstrating that there was at least one workweek in which they worked in excess of forty hours and were not paid overtime wages." Id. Because the plaintiff "identified tasks for which he was not paid and alleged that he regularly worked more than eight hours in a day and forty hours in a week," his allegations "satisf[ied] the pleading requirements of Landers at this stage of the litigation." Id.

\*3 Boon's reasoning is persuasive because it harmonizes Landers with Federal Rule of Civil Procedure 8's general pleading standard that plaintiffs must plead more than "labels and conclusions," but need not undertake the "cumbersome"

practice of "set[ting] out in detail the facts upon which he bases his claim." Twombly, 550 U.S. at 555 & n.3. Requiring plaintiffs to allege specific dates, actual (or approximate) amounts of wages, corresponding violations, and other data giving rise to their claims would rachet up the general pleading standard such that it would resemble the Rule 9 particularity standard, which, in contrast to Rule 8, mandates that plaintiffs state the "the who, what, when, where, and how" of their claims. Cafasso, U.S. ex rel. v. Gen. Dynamics C4 Sys., Inc., 637 F.3d 1047, 1055 (9th Cir. 2011). The Court does not read Landers to require such heightened particularity. See Landers, 771 F.3d at 644 ("Although we agree ... that detailed factual allegations regarding the number of overtime hours worked are not required to state a plausible claim, we do not agree that conclusory allegations that merely recite the statutory language are adequate."). The Court therefore will follow Boon in analyzing Sagastume's meal break, rest break, overtime pay, and minimum wage claims.

#### **B.** Overtime Violations (Claim 1)

California Labor Code section 510 states "[e]ight hours of labor constitutes a day's work. Any work in excess of eight hours in one workday and any work in excess of 40 hours in any one workweek" requires employers to pay employees "at the rate of no less than one and one-half times" their regular rate. Cal. Lab. Code § 510. Sagastume alleges she and other class members worked in excess of eight hours a day or forty hours a week performing work duties off the clock, "such as performing data entry, analyzing hair samples, weighing hair samples, cleaning and organizing work station, gathering supplies necessary for work-related tasks, [and] receiving and answering work-related questions from supervisors and managers." FAC ¶ 55. Sagastume alleges, "[b]y way of example," that she was not compensated at an overtime rate for excess time worked "during the period of approximately October 2016 to November 2016." Id. Psychemedics argues that the allegations are not specific enough under Landers and the claim is prohibited by the statute of limitations.

At this stage of litigation, the allegations are sufficient. Sagastume alleges that she worked in excess of eight hours a day or in excess of forty hours a week and lists work duties she performed off the clock, including from October to November 2016. In <u>Boon</u>, the Ninth Circuit found that allegations that "identified tasks for which [plaintiff] was not paid and alleged that [plaintiff] regularly worked more than eight hours in a day and forty hours in a week" were sufficient to plead an overtime claim. 592 F. App'x at 632.

Additionally, the Court does not find Psychemedics' statute of limitations argument persuasive. The statute of limitations for Sagastume's overtime claim is three years from the date when the most recent violation occurred. Cal. Civ. Proc. § 338(a). Psychemedics argues that "assuming Plaintiff experienced an overtime violation on November 30, 2016, she had until November 30, 2019 to file her Complaint" but did not do so until June 9, 2020. Mot. at 12. In other words, Psychemedics takes the October 2016 to November 2016 dates that are given only "by way of example" as the last time that Sagastume worked overtime and was not properly compensated for it. Given that Sagastume was employed by Psychemedics until November 2017, and the FAC alleges that the overtime violations happened "[d]uring the relevant time period," FAC ¶ 55, the Court finds that the statute of limitations does not bar this claim.

The motion to dismiss the First Cause of Action is DENIED.

# C. Meal and Rest Break Violations (Claims 2 and 3)

Sagastume alleges that Psychemedics failed to comply with the California Labor Code by failing to provide required meal and rest breaks in violation of California Labor Code section 512(a) and the applicable Industrial Welfare Commission Wage Order and failing to provide the compensation required when Sagastume worked during those meal and rest breaks. FAC ¶¶ 64-69, 76-79.

\*4 Psychemedics argues its strict interpretation of the Landers standard applies to meal and rest break claims and Sagastume's allegations fail because Sagastume has not pled facts showing there was a given week in which meal and rest break violations occurred. Mot. at 12-13. The FAC does not identify any specific period or week in which Sagastume was not permitted to take her meal and rest breaks or such breaks were interrupted other than "during the relevant time period." As Boon suggests, however, Landers does not require the type of specificity that Psychemedics demands. As in Boon, Sagastume has described "tasks for which [s]he was not paid" and has alleged that Psychemedics "regularly" violated the provisions giving rise to her claim, Boon, 592 F. App'x at 632 - even identifying that the violations happened four times a week, FAC ¶ 76. These allegations satisfy Landers' pleading requirements.

The motion to dismiss the Second and Third Causes of Action is DENIED.

# D. Minimum Wage Violations (Claim 4)

Sagastume's minimum wage claim is premised on the same facts as her overtime pay – that she worked time off the clock for which she was not paid, including during the period of approximately October 2016 to November 2016. FAC ¶ 84. Psychemedics argues that "[t]his claim suffers the same fate as the overtime claim" for the same reasons – it does not meet the standard articulated in <u>Landers</u> and was not brought within the statute of limitations. Mot. at 13-14. As explained above, the Court rejects those arguments and, consequently, DENIES the motion as to the Fourth cause of Action.

# E. Failure to Pay All Wages at Resignation or Termination (Claim 5)

Sagastume claims, under California Labor Code sections 201, 202, and 203, that Psychemedics failed to pay her all wages due on separation because it failed to pay her for "wages earned and unpaid throughout her employment, including but not limited to, minimum wages and overtime wages for time worked off-the-clock and meal and rest period premium payments." FAC ¶ 91. Psychemedics argues the claim fails because it is derivative of the first four claims, which all fail to state a claim. Mot. at 14. Psychemedics also alleges Sagastume "fails to plead any specific factual allegations to plausibly suggest that Defendant refused to pay final wages to Plaintiff," facts about Sagastume's termination, or facts supporting that Psychemedics' "purported violation was willful for purposes of imposing waiting time penalties under Section 203." Id.

The claim does not fail as a derivative of the first four claims because those claims are adequately pleaded. Further, there is no requirement that a plaintiff plead details of her own termination, such as "the date she received her final paycheck," id., and Psychemedics cites no authority to establish that requirement. Psychemedics' citation to Sanchez v. Aerogroup Retail Holdings, Inc., No. 12-CV-05445-LHK, 2013 WL 1942166 (N.D. Cal. May 8, 2013), is also unpersuasive. There, the plaintiff pleaded only: "Plaintiff and all members of Class IV who terminated their employment without being paid all wages due upon termination are entitled to penalties up to and including 30 days of full pay as waiting penalties." Id. at \*14. Here, by contrast, Sagastume alleges Psychemedics' practice of requiring Sagastume to work off the clock during meal periods, rest periods, and overtime. In Varsam, the district court, analyzing similar allegations, found "it can reasonably be inferred that Defendant deliberately

failed to pay wages that it knew were owed." <u>Varsam</u>, 120 F. Supp. 3d at 1179.

The Court DENIES the motion to dismiss as to Sagastume's Fifth Cause of Action

# F. Failure to Pay Wages During Employment (Claim 6)

Next, Sagastume alleges under California Labor Code section 204, that Psychemedics failed to pay her and other class members all wages due. FAC ¶¶ 95-99. Psychemedics argues Sagastume "does not identify which wages Defendant allegedly failed to pay, but assuming she is referring to overtime and minimum wages, she has failed to state claim for those violations." Mot. at 15.

\*5 As stated above, the Court has found that Sagastume has adequately pleaded her overtime and minimum wage claims. It therefore DENIES the motion to dismiss as to the Sixth Cause of Action.

# G. Failure to Provide Accurate Wage Statements (Claim 7)

California Labor Code section 226(a) requires employers to furnish to employees "an accurate itemized statement in writing" showing nine specific items. Cal. Lab. Code § 226(a). If an employee suffers injury by an employer's knowing and intentional failure to provide such information, she is entitled to recover damages. Id. § 226(e).

Sagastume alleges that Psychemedics "intentionally and willfully failed to provide Plaintiff and the other class members with complete and accurate wage statements" including by failing "to include the accurate total number of hours worked by Plaintiff and the other class members." FAC ¶ 103. This claim, therefore, is derivative of Sagastume's claims for relief for overtime and minimum wage. Psychemedics argues the claim is thus a claim for impermissible double recovery. Mot. at 15.

In Maldonado v. Epsilon Plastics, Inc., 22 Cal. App. 5th 1308, 1336-37 (2018), the California Court of Appeal held plaintiffs could not recover on a wholly derivative wage statement claim under section 226. In that case, plaintiffs were not properly paid overtime. Id. at 1335. The trial court awarded plaintiffs penalties for inaccurate wage statements because the wage statements documented the improper overtime wage rates. Id. at 1334. Defendant argued "failure to pay overtime, "not

from the inaccurate wage statements." <u>Id.</u> at 1335. Therefore, the "only way [defendant] could have avoided wage statement penalties ... would have been to issue a wage statement which bore no similarity to the pay the employees were actually receiving." <u>Id.</u> at 1336. The court agreed with defendant and remanded to the trial court to eliminate the award for wage statement penalties. <u>Id.</u> at 1336, 1339.

District courts ruling on this issue have split on whether the logic of Maldonado applies equally to claims like the one here, where the inaccuracy was based on the employer not accounting for all hours worked rather than paying the wrong rate. Compare Parsittie v. Schneider Logistics, Inc., No. CV 19-3981-MWF (AFMx), 2020 WL 2120003, at \*8 (C.D. Cal. Apr. 3, 2020) ("Plaintiff's Opposition admits that his wage statement claim is based on the same theories as his claims for unpaid wages and missed breaks, which is impermissible.") and Krauss v. Wal-Mart, Inc., No. 2:19-cv-00838-JAM-DB, 2019 WL 6170770, at \*4 (E.D. Cal. Nov. 20, 2019) (holding a claim was "forbidden" because it was derivative of plaintiff's "meal period, rest breaks, and overtime" claims) with Fodera v. Equinox Holdings, Inc., No. 19-cv-05072-WHO, 2020 WL 3961985, at \*5 (N.D. Cal. July 13, 2020) (holding plaintiffs' allegation "that the wage statements do not reflect all hours that they worked" is not a claim for double recovery) and Castillo v. Bank of Am. Nat'l Ass'n, No. SA CV 17-0580-DOC (KESx), 2019 WL 7166055, at \*8 (C.D. Cal. Oct. 29, 2019) (holding Maldonado is inapposite because there, "the plaintiffs argued that the wage statement was inaccurate not because it did not include all hours plaintiffs worked, but because it did not correctly apportion the rate of pay for those hours").

\*6 While Maldonado does not dictate the result here, the Court finds its reasoning persuasive. "The purpose of requiring greater wage stub information is to insure that employees are adequately informed of *compensation received* and are not shortchanged by their employers." Maldonado, 22 Cal. App. 5th at 1337 (quoting Cal. Assemb. Comm. on Lab. & Emp., Analysis of Sen. B. No. 1255 (2011-2012 Reg. Sess.)). Sagastume does not allege the wage statements inaccurately documented the amount of money she actually *received*. Instead, she argues only that they are inaccurate because Psychemedics was improperly compensating her. Recovery on her wage statements claim then would be impermissible double recovery for her hours worked claims.

District courts not applying <u>Maldonado</u> in this context point to a line in <u>Maldonado</u> in which the appellate court emphasized

there is "clearly a significance to the Legislature's decision that injury is not presumed when a wage statement fails to include wages 'earned' but is presumed when the wage statement fails to include hours 'worked at' a particular rate."

Id. at 1336. However, as the court in Castro v. Wal-Mart, Inc. articulated, claims like this for time spent "off the clock" are "based on 'wages earned' since [the] allegation for failure to compensate off-the-clock work will be remedied by [a] wage and hour claim." No. 2:20-cv-00928-JAM-KJN, 2020 WL 4748167, at \*2 (E.D. Cal. Aug. 17, 2020). This is consistent with the purpose of section 226 – to "document the paid wages to ensure the employee is fully informed regarding the calculation of those wages." Soto v. Motel 6 Operating, L.P., 4 Cal. App. 5th 385, 392 (2016).

Sagastume's Seventh Cause Of Action is DISMISSED with leave to amend.

# H. Failure to Maintain Records (Claim 8)

Sagastume alleges Psychemedics failed to accurately maintain her and other class members' time records in violation of California Labor Code section 1174(d). FAC ¶¶ 111-113. Psychemedics moves to dismiss Sagastume's recordkeeping claim on the grounds she has not pled a legally viable cause of action. Mot. at 18-19.

District courts have found that plaintiffs cannot state a claim under section 1174 unless they seek civil penalties through the Private Attorney Generals Act (PAGA). Guerrero v. Halliburton Energy Servs., Inc., No. 1:16-CV-1300-LJO-JLT, 2016 WL 6494296, at \*7 (E.D. Cal. Nov. 2, 2016); Silva v. U.S. Bancorp, No. 5:10-cv-01854-JHN-PJWx, 2011 WL 7096576, at \*3 (C.D. Cal. Oct. 6, 2011) ("[T]he Court dismisses with prejudice Plaintiff's recordkeeping claim to the extent it alleges a stand-alone violation of the Wage Order because it is not a legally cognizable claim."). Sagastume argues that by bringing a UCL claim, she makes this violation "independently actionable." Opp'n at 17 (citing Rose v. Bank of Am., N.A., 57 Cal. 4th 390, 396 (2013)). While the UCL does "borrow" violations of other laws and make them actionable, such a claim must be brought as a UCL claim and not a claim under the independent statute. It is not enough – as Sagastume appears to argue – that she also separately pleads an independent UCL claim.

Because Sagastume does not bring a PAGA claim, the Court finds that she has failed to state a claim and DISMISSES her Eighth Cause of Action without leave to amend.

# I. Failure to Reimburse Business Expenses (Claim 9)

California Labor Code section 2802 requires employers to indemnify "employee[s] for all necessary expenditures or losses incurred by the employee[s] in direct consequence of the discharge of [their] duties." Cal. Lab. Code § 2802. There are three elements to a claim under section 2802: "(i) the employee made expenditures or incurred losses; (ii) the expenditures or losses were incurred in direct consequence of the employee's discharge of his or her duties, or obedience to the directions of the employer; and (iii) the expenditures or losses were reasonable and necessary." Marr v. Bank of Am., No. C 09-05978 WHA, 2011 WL 845914, at \*1 (N.D. Cal. Mar. 8, 2011), aff'd 506 F. App'x 661 (9th Cir. 2013) (citing Gattuso v. Harte-Hanks Shoppers, Inc., 42 Cal. 4th 554, 568 (2007)). Sagastume does not plausibly plead the latter two elements.

\*7 Sagastume alleges that she and others incurred business expenses and costs that were not fully reimbursed "including but not limited to the use of personal phones for businessrelated purposes, costs incurred to purchase supplies for business-related purposes, and costs incurred using their personal vehicles for work travel." FAC ¶ 117. Psychemedics argues that Sagastume does not state a claim because the "FAC does not allege a single instance when such expenses were incurred, whether the expenses were necessary, whether Plaintiff requested reimbursement for the expenses, and whether Defendant failed to reimburse." Mot. at 19.

In Franke v. Anderson Merchandisers LLC, this Court found allegations of expenses that "included use of personal phones for business-related purposes, costs incurred to comply with Defendants' dress code, and costs incurred using their personal vehicles for work travel" were insufficient because the plaintiff "fail[ed] to provide a single instance when such a cost was incurred" and "without facts regarding the nature of [plaintiff's] position – or of the expenses – the Court [could not] reasonably infer these expenses were necessary for business purposes." No. CV 17-3241 DSF (AFMx), 2017 WL 3224656, at \*7 (C.D. Cal. July 28, 2017) (internal quotation marks omitted).

Here Sagastume also has failed to provide sufficient information about her job and duties for the Court to infer why she would require the use of her vehicle and cell phone for work-related purposes, or what supplies she needed to purchase. Her pleading is therefore inadequate. The cases she cites in support of her argument do not require a different outcome as they generally involve more detailed allegations. For instance, in Saunders v. Ameriprise Financial Services, Inc., the plaintiff alleged that as a financial advisor, paying for referral fees to generate business was an integral part of his job function. No. CV 18-10668-MWF (AFMx), 2019 WL 4344296, at \*3 (C.D. Cal. Mar. 19, 2019). The court found those allegations sufficient because a plaintiff need not "provide a detailed list of every business expense incurred, when they were incurred, the amount, or whether they were necessary and incurred in direct consequence of the discharge of his duties." Id. at \*4 (internal quotation marks omitted).

The Court DISMISSES Sagastume's Ninth Cause of Action with leave to amend.

# J. UCL Violation (Claim 10)

Psychemedics contends Sagastume fails to state a UCL claim because Sagastume "fails to allege that she lacks an adequate legal remedy." Mot. at 11. The Ninth Circuit recently held that a plaintiff "must establish that she lacks an adequate remedy at law before securing equitable restitution for past harm under the UCL." Sonner v. Premier Nutrition Corp., 971 F.3d 834, 844 (9th Cir. 2020). In Sonner, the Ninth Circuit affirmed a district court's dismissal of claims for equitable restitution under the UCL where "the operative complaint d[id] not allege that [plaintiff] lacks an adequate legal remedy" and the plaintiff "concede[d] that she seeks the same sum in equitable restitution ... as she requested in damages to compensate her for the same past harm." Id.

Sagastume is correct that "Sonner does not hold that plaintiffs may not seek alternative remedies at the pleading stage." Opp'n at 7; see Eason v. Roman Cath. Bishop of San Diego, 414 F. Supp. 3d 1276, 1282 (S.D. Cal. 2019) ("allowing plaintiffs to plead a UCL claim as an alternative legal remedy" as "[n]o controlling authority prevents a plaintiff from pleading alternative legal remedies"). However, whether a UCL claim is pleaded as the sole or an alternative remedy, it must be pleaded adequately. Therefore, in order to adequately assert a claim for equitable restitution under the UCL in federal court, the complaint must allege that Sagastume lacks an adequate legal remedy. The FAC does not.<sup>2</sup>

- 2 Sagastume also attempts to distinguish Sonner based on differences in procedural posture. Opp'n at 6-7. The principal Sonner establishes, however, remains the same.
- \*8 The Court DISMISSES Sagastume's tenth claim with leave to amend.

# K. Injunctive Relief

Finally, Psychemedics argues Sagastume is not entitled to injunctive relief because past employees lack standing to pursue injunctive relief against their former employers. Mot. at 20. "To have standing to bring a claim for relief, a plaintiff must show she has (1) suffered an injury that (2) was caused by the defendant and (3) is likely to be redressed by the relief she seeks." Walsh v. Nev. Dep't of Hum. Res., 471 F.3d 1033, 1036-37 (9th Cir. 2006). A former employee who has no plans to return to work for their former employee does not have standing because "she would not stand to benefit from an injunction." Id. at 1037; see also Gordon v. Aerotek, Inc., No. ED CV 17-0225-DOC (DTBx), 2017 WL 8217410, at \*5-6 (C.D. Cal. Oct. 12, 2017) (collecting cases). Sagastume argues that the court should allow for injunctive relief because California "allows the courts 'broad discretion is fashioning relief,' including injunctive relief' if it is in the interest of public policy. Opp'n at 19 (quoting Rosenberg v. Renal Advantage, Inc., No. 11-cv-2152-GPC-KSC, 2013 WL 3205426, at \*10 (S.D. Cal. June 24, 2013)). This may be true, but a state statute or policy "cannot alter the constitutional standing requirements of federal courts, even if for good public policy reasons." Gordon, 2017 WL 8217410, at \*5; see also Hangarter v. Provident Life & Accident Ins. Co., 373 F.3d 998, 1022 (9th Cir. 2004) ("[A] plaintiff whose cause of action ... is perfectly viable in state court under state law may nonetheless be foreclosed from litigating the same cause of action in federal court, if he cannot demonstrate the requisite

injury to establish Article III standing." (internal quotation marks omitted)).

The Court therefore DISMISSES any requests for injunctive relief within the FAC.

#### IV. CONCLUSION

Psychemedics' motion to dismiss Sagastume's claims is GRANTED in part and DENIED in part. The Seventh, Ninth, and Tenth Causes of Action are DISMISSED with leave to amend. The Eighth Cause of Action and any requests for injunctive relief are DISMISSED without leave to amend. An amended complaint must be filed no later than December 30, 2020. Failure to file by that date will waive the right to do so. If Plaintiff fails to file an amended complaint by that date, Defendant must answer the remaining causes of action within twenty days after that date. Leave to amend is granted only to address the specific issues raised by the motion. The Court does not grant leave to add new defendants or new claims. Plaintiff must seek such leave to amend by a properly noticed motion.

IT IS SO ORDERED.

# **All Citations**

Slip Copy, 2020 WL 8175597

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# **Tab 27**

KeyCite Yellow Flag - Negative Treatment

Distinguished by Vertex Refining, NV, LLC v. National Union Fire
Insurance, Company of Pittsburgh, PA, N.D.III., March 14, 2017

2010 WL 1506709

Only the Westlaw citation is currently available.

United States District Court,

N.D. Illinois,

Eastern Division.

Kathy SEFTON, on behalf of herself and all others similarly situated, Plaintiffs

V.

TOYOTA MOTOR SALES U.S.A.,
Inc., a California corporation,
Autonation, Inc., a Florida corporation,
and Libertyville Toyota, an
Illinois corporation, Defendants.

No. 09 C 3787. | April 14, 2010.

West KeySummary

# 1 Sales ← Participation in and relation to transaction

Car buyer could not maintain breach of contract action against car manufacturer, under Illinois law, based on allegation that the manufacturer misrepresented the car's navigational features. Buyer did not sufficiently allege that the manufacturer was a party to the contract in question. Buyer did allege that the manufacturer made the offer creating the contract and breached, but this did nothing more than parrot the elements necessary to prove the cause of action. Further, the allegations were contradicted by the actual contract which listed only the buyer and the dealership as parties.

8 Cases that cite this headnote

# **Attorneys and Law Firms**

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#### **MEMORANDUM OPINION AND ORDER**

#### REBECCA R. PALLMEYER, District Judge.

\*1 Plaintiff Kathy Sefton claims the Toyota RAV4 she purchased lacks a valuable navigation feature. She filed this action on behalf of a class of purchasers against Defendants Toyota Motor Sales USA, Inc., Autonation, Inc., and Libertyville Toyota. Plaintiff alleges that when she purchased her 2009 Toyota RAV4 from Libertyville Toyota, she spent about \$4,000 for an extra value package that Defendants represented would include XM NavTraffic capability. In fact, Plaintiff alleges, with or without the extra package, the RAV4 cannot support a NavTraffic system. Plaintiff asserts five claims on behalf of herself and the purported class, seeking damages for Defendants' alleged misrepresentation. Defendants move to dismiss Plaintiff's complaint. For the reasons that follow, the motion is granted as to all claims except the claim for breach of contract against Defendant Libertyville Toyota.

#### FACTUAL BACKGROUND

On a motion to dismiss, the court must "accept as true all well-pleaded facts alleged, drawing all possible inferences in the plaintiff's favor." *Lake v. Neal*, 585 F.3d 1059, 1060 (7th Cir.2009). Plaintiff purchased the 2009 Toyota RAV4 from Defendant Libertyville Toyota in November 2008. (Compl.¶ 11.) Defendant AutoNation owns Libertyville Toyota and employs its staff. (*Id.* ¶¶ 4–5.) Defendant Toyota Motor Sales is the sales, distribution, and marketing unit for Toyota Motor Corporation; it is responsible for advertising, marketing materials, and supervising dealer marketing. (*Id.* ¶¶ 3, 9.)

The court notes that federal jurisdiction is not disputed even though Plaintiff and Defendant Libertyville Toyota are both Illinois citizens. The Class Action Fairness Act

of 2005 creates federal jurisdiction over certain state class actions in cases where diversity jurisdiction is not complete, so long as at least one member of the class is a citizen of a different state from any defendant. 28 U.S.C. § 1332(d). And the Seventh Circuit has held that such jurisdiction does not depend on class certification. Cunningham Charter Corp. v. Learjet, Inc., 592 F.3d 805, 806 (7th Cir.2010). Plaintiff's preliminary class definition is "[a]ll consumers throughout the United States who purchased a 2009 RAV4 and/or a 2009 RAV4 with Package # 2." (Compl.¶ 17.) Plaintiff has made no allegations regarding the citizenship of members of the proposed class, but for purposes of this ruling, the court assumes that the proposed class includes at least one member who has claims against all Defendants and is a citizen of a state that is not Illinois, California, or Florida —the states of citizenship for the three Defendants—and, therefore, jurisdiction is proper.

Without specifically identifying the persons(s) she negotiated with, Plaintiff alleges that when she purchased the vehicle, she had a choice between two "Limited Extra Value Packages." (Compl.¶ 12.) Plaintiff chose Package # 2 and paid \$4,110 for it. (*Id.* ¶ 13.) At the time of the purchase, Defendants represented to Plaintiff that the RAV4 and/or Package # 2 was XM NavTraffic capable. [Id.¶ 14.] The representations were made by AutoNation's and Libertyville Toyota's employees and signs, and by Toyota Motor Sales's online, print advertising, manuals, and signs. (*Id.*) After the purchase, Plaintiff made several trips to Libertyville Toyota before finally learning that her RAV4 was not NavTraffic capable with or without Package # 2. (*Id.*¶ 15.)

XM NavTraffic is a subscription service that broadcasts live traffic information to a vehicle's navigation system. XM Satellite Radio—XM NavTraffic Overview, http:// www.xmradio.com/navtraffic/ (last visited April 14, 2010).

Plaintiff brought this lawsuit, alleging breach of contract (Count I); unjust enrichment (Count II); violation of the Illinois Consumer Fraud and Deceptive Business Practices Act ("ICFA"), 815 ILCS 505/2 (2006) (Count III); and breach of express warranty (Count IV); and she seeks an accounting (Count V). She seeks to represent a class, preliminarily defined as:

All consumers throughout the United States who purchased a 2009 RAV4 and/or a 2009 RAV4 with Package # 2. The class does not include Defendants, or their officers, directors, agents or employees.

(Compl.¶ 17.) Defendants filed a motion to dismiss the complaint for failure to state a claim, and Plaintiff filed a motion for class certification. The court continued Defendants' motion for briefing and continued Plaintiff's motion pending discovery. The parties have filed their briefs on Defendants' motion.

# **DISCUSSION**

\*2 To survive a motion to dismiss for failure to state a claim, a complaint must contain "a short and plain statement of the claim showing that the pleader is entitled to relief." Fed. R. Civ. P. 8(a)(2). Detailed factual allegations are not required, but the plaintiff must provide enough facts "to raise a right to relief above the speculative level." *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 555, 127 S.Ct. 1955, 167 L.Ed.2d 929 (2007). The plaintiff must present "more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do." *Id.; see also Ashcroft v. Iqbal*, — U.S. —, 129 S.Ct. 1937, 173 L.Ed.2d 868 (2009); *Brooks v. Ross*, 578 F.3d 574, 580–81 (7th Cir.2009).

# A. Breach of Contract (Count I)

Under Illinois law, to state a claim for breach of contract, Plaintiff must allege "(1) the existence of a valid and enforceable contract; (2) substantial performance by the plaintiff; (3) a breach by the defendant; and (4) resultant damages." TAS Distributing Co. v. Cummins Engine Co., 491 F.3d 625, 631 (7th Cir.2007) (citing W.W. Vincent & Co. v. First Colony Life Insurance Co., 351 Ill.App.3d 752, 759, 286 Ill.Dec. 734, 814 N.E.2d 960, 967 (1st Dist.2004)). "A court must initially look to the language of a contract alone, as the language, given its plain and ordinary meaning, is the best indication of the parties' intent." Gallagher v. Lenart, 226 Ill.2d 208, 233, 314 Ill.Dec. 133, 874 N.E.2d 43, 58 (2007). Under the parol-evidence rule, extrinsic evidence of the contract's meaning may be considered only if the language of the contract is ambiguous, that is, susceptible to more than one meaning. Id.

Defendants first argue that Plaintiff has pleaded herself out of court because the contract attached to her complaint as Exhibit A says nothing about NavTraffic capabilities. (Defs' Br. at 3–4.) The contract also says nothing about the Limited Extra Value Package, for which Plaintiff alleges she paid \$4,110. (Compl.¶¶ 13–15.) Drawing inferences in Plaintiff's favor, as required at this stage, the court assumes that Plaintiff's

purchase of the package is reflected in the cash price of \$33,117 set forth in the contract. (Id., Ex. A.) That amount appears on a line of the printed form beside the words "Cash Price (including any accessories, services and taxes.)" (Id.) But no accessories, services, or taxes are enumerated in the contract. Because the word "accessories" is not defined in the contract, and because Plaintiff has alleged that she had a choice between two accessory packages, (id., ¶ 12, 314 Ill.Dec. 133, 874 N.E.2d 43), that term is ambiguous. Plaintiff has alleged that the contract included a promise that the vehicle had NavTraffic capability, (id., ¶ 12, 14, 314 Ill.Dec. 133, 874 N.E.2d 43), and on a motion to dismiss for failure to state a claim, the court must assume the truth of the Plaintiff's allegations. Lake, 585 F.3d at 1060. Thus, Plaintiff has sufficiently alleged that NavTraffic capability was a part of the contract and has satisfied the first elements of her claim for breach of contract.

\*3 Defendants do not challenge any of the other elements of the claim, but they do argue that Defendants Toyota Motor Sales and AutoNation cannot be liable for breach of contract because they were not parties to the contract. (Defs' Br., at 4.) Indeed, Exhibit A is a contract between Plaintiff and Libertyville Toyota, and Plaintiff's Complaint alleges that she purchased the vehicle from Libertyville Toyota. (Compl.¶ 11, Ex. A.) Plaintiff points out that the contract is for a Toyota vehicle, states that it will be assigned to Toyota Motor Credit Corporation, and bears the Toyota logo accompanied by the words "Toyota Financial Services" in the upper right corner. (Pl's Br., at 8.) Plaintiff has not, however, alleged any connection between Toyota Motor Credit Corporation or Toyota Financial Services and Defendants Toyota Motor Sales or AutoNation. Nor is the appearance of the Toyota name or logo on a contract sufficient, without more, to make Toyota Motor Sales a party to the contract. Meeker v. Gray, 142 Ill.App.3d 717, 727–28, 97 Ill.Dec. 72, 492 N.E.2d 508, 515 (5th Dist.1986) (defendant who was not a party to a contract could not be held jointly and severally liable with codefendants who were parties); see also Thomas v. Caldwell, 50 Ill. 138, 1869 WL 5188, at \*1 (1869) (mere appearance of individual's name in body of contract did not make individual a party to the contract). Similarly, Plaintiff's argument that by making false representations about the contract all Defendants became a party to it must also fail. Plaintiff cites no authority for the proposition that a party can be bound by a written contract merely because that party made false representations about the contract's terms.

Plaintiff's alternative argument is that she has included allegations that, in her view, are sufficient to state a claim that Toyota Motor Sales and AutoNation are parties to the contract. (Pl's Br., at 7–8.) The complaint does include allegations that all Defendants made the offer creating the contract and that all Defendants breached the contract, (id. ¶ 24–27), but these conclusory allegations are insufficient to survive a motion to dismiss because they do nothing more than parrot the elements necessary to prove the cause of action. *Twombly*, 550 U.S. at 555 (plaintiff must plead "more than labels and conclusions"). Moreover, they are contradicted by Exhibit A, the contract attached to Plaintiff's complaint, which, as explained, lists only Plaintiff and Libertyville Toyota as parties.

Finally, Plaintiff argues that even if she cannot hold Toyota Motor Sales and AutoNation liable as parties to the contract, they can be held liable based on an agency relationship with Libertyville Toyota. (Pl's Br., at 8, 16.) "An agent is one who undertakes to manage the affairs of another, on the authority and for the account of the latter, who is called the principal, and to render an account to the principal." Eychaner v. Gross, 202 Ill.2d 228, 258, 269 Ill.Dec. 80, 779 N.E.2d 1115, 1134 (2002). With respect to Toyota Motor Sales, the agency theory is unsupported; Plaintiff has not alleged a connection between Toyota Motor Sales and Libertyville Toyota. She has offered a link to AutoNation, specifically alleging that Libertyville Toyota is owned by, operated by, and is an agent of AutoNation. (Id. ¶¶ 5, 10, 269 Ill.Dec. 80, 779 N.E.2d 1115.) In Plaintiff's view, this allegation is sufficient. She contends that the question of agency is a factual question on which discovery is needed, and that the court should decline to dismiss the complaint as against AutoNation on this basis. Even before Twombly, however, courts in this district held that pleading the existence of an agency relationship requires more than a general statement that such a relationship exists. Azimi v. Ford Motor Co., 977 F.Supp. 847, 851 (N.D.III.1996); Rand Bond of North America, Inc. v. Saul Stone & Co., 726 F.Supp. 684, 687 (N.D.III.1989). Although she asserts generally that AutoNation is responsible for some of the misrepresentations in question, she has not made any allegations concerning an actual agency relationship beyond purely conclusory statements. (Compl. ¶ 5, 10) Thus, her complaint is insufficient to plead an agency relationship. Cf. Semitekol v. Monaco Coach Corp., 582 F.Supp.2d 1009, 1025 (N.D.III.2008) (complaint sufficiently alleged agency relationship between dealership and manufacturer where plaintiff alleged, among other allegations, that dealership was held out to be authorized dealership for manufacturer,

that manufacturer advised buyers to contact dealership for customer service, and that buyers had the option to pick up the purchased item from the dealership or from the manufacturer).

\*4 In support of the agency theory, Plaintiff has also argued for direct-participant liability against AutoNation as Libertyville Toyota's corporate parent, but that argument fails because she has alleged only that AutoNation made unspecified misrepresentations to her. (Pl's Br., at 16.) She has not alleged that AutoNation exercised any control over Libertyville Toyota beyond the "control exercised as a normal incident of ownership." *Forsythe v. Clark USA, Inc.*, 224 Ill.2d 274, 290, 309 Ill.Dec. 361, 864 N.E.2d 227, 237 (2007). For all these reasons, Defendants' motion is granted as to Count One except against Defendant Libertyville Toyota.

# **B.** Illinois Consumer Fraud and Deceptive Business Practices Act (Count III)

To succeed on a claim under the ICFA, a plaintiff must show "(1) a deceptive act or practice by the defendant, (2) the defendant's intent that the plaintiff rely on the deception, (3) the occurrence of the deception in the course of conduct involving trade or commerce, and (4) actual damage to the plaintiff (5) proximately caused by the deception." Avery v. State Farm Mut. Auto. Ins. Co. ., 216 Ill.2d 100, 180, 296 Ill.Dec. 448, 835 N.E.2d 801, 850 (2005). An ICFA claim differs from a common law fraud claim in that the Plaintiff need not show reliance on the deception. Connick v. Suzuki Motor Co., 174 Ill.2d 482, 501, 221 Ill.Dec. 389, 675 N.E.2d 584, 593 (1996). As with a common law fraud claim, however, a plaintiff alleging a violation of ICFA is subject to a heightened pleading standard. Under Federal Rule of Civil Procedure 9(b), the complaint "must state with particularity the circumstances constituting fraud or mistake." Crichton v. Golden Rule Ins. Co., 576 F.3d 392, 395 (7th Cir.2009); Centerline Equipment Corp. v. Banner Personnel Service, Inc., 545 F.Supp.2d 768, 778–79 (N.D.III.2008). The Seventh Circuit has explained the particularity requirement by reference to the first paragraph of a newspaper article; the complaint must include "the who, what, when, where, and how." DiLeo v. Ernst & Young, 901 F.2d 624, 627 (7th Cir.1990). That is, it must include " 'the identity of the person who made the misrepresentation, the time, place and content of the misrepresentation, and the method by which the misrepresentation was communicated to the plaintiff.' " Windy City Metal Fabricators & Supply, Inc. v. CIT Technology Financing Services, Inc., 536 F.3d 663, 668 (7th Cir.2008) (quoting General Electric Capital Corp. v. Lease Resolution Corp., 128 F.3d 1074, 1078 (7th Cir.1997)).

Defendants argue that Plaintiff's allegations fail to satisfy Rule 9(b)'s heightened pleading requirement. (Defs' Br., at 6–7.) Plaintiff disagrees, (Pl's Br. at 10), pointing first to Paragraph 14 of her complaint:

At the time of Plaintiff's purchase, Defendants falsely represented to Plaintiff that the RAV4 and/or Package # 2 was XM NavTraffic ("NavTraffic") capable. Said representations were made to Plaintiff by and through AutoNation's and [Libertyville Toyota]'s employees and signage, and Toyota's online and print advertising, owner's manual and signage.

\*5 (Compl.¶ 14.) This paragraph is insufficient to satisfy Rule 9(b) for several reasons. First, it does not identify any specific communications, nor point to the particular signs, advertisements, or manuals that were responsible for the misrepresentation. Cf. Dubicz v. Commonwealth Edison Co., 377 F.3d 787, 794–95 (7th Cir.2004) (complaint satisfied Rule 9(b) because it identified the misrepresentations at issue, the specific dates on which they were made, and the specific persons responsible for making them). Nor has Plaintiff identified the person(s) who made the misrepresentation; her complaint alleges that she had the option of selecting a package that included the XM NavTraffic capability, (Compl. 12), but she does not explain who gave her that option. Finally, Plaintiff argues that the "packet" of materials she submitted as Exhibit B adequately alleges her ICFA claim with the required particularity. (Pl's Br., at 10.) That "packet" is a single page printout from an unidentified website that appears to list the optional packages available to a purchaser of a 2009 RAV4. (Compl.Ex. B.) Under the ICFA, Plaintiff need not allege that she read or relied on that printout, but under Rule 9(b), she must allege the "who, what, when, where, and how" of the printout. DiLeo, 901 F.2d at 627. She has not done so here. For all these reasons, Plaintiff's ICFA claim must be dismissed.

# C. Breach of Express Warranty (Count IV)

In challenging the sufficiency of Plaintiff's claim for breach of express warranty, Defendants first argue that she failed to allege that she notified them of the breach. (Defs' Br., at 7.) The notification requirement, 810 ILCS 5/2–607(3)(a), can be excused if "the seller has actual knowledge of the defect of the particular product" or "the seller is deemed to have been reasonably notified by the filing of the buyer's complaint alleging breach of UCC warranty." *Connick v. Suzuki Motor* 

Co., 174 Ill.2d 482, 492, 221 Ill.Dec. 389, 675 N.E.2d 584, 589 (1996). Plaintiff argues that her complaint sufficiently alleges satisfaction of the notification requirement and that, in the alternative, she can meet the first exception to the requirement. (Pl's Br., at 14.)

Plaintiff alleged the following: "After several trips to and from [Libertyville Toyota], Plaintiff learned that the RAV4 is not NavTraffic capable with or without Package # 2." (Compl. 15.) This allegation is plainly insufficient to establish that Plaintiff notified Defendants of the breach. To give notice, the buyer "must directly notify the seller of the troublesome nature of the transaction," and Plaintiff's vague allegation that at some point she herself became aware of the problems with the vehicle says nothing about her communication with Defendants concerning those problems. Connick, 174 III.2d at 492, 221 III.Dec. 389, 675 N.E.2d at 589. Plaintiff suggests that notice was unnecessary in this case because Defendants knew about the defect, but her complaint does not include such an allegation. That Plaintiff herself became aware that the RAV4 is not NavTraffic capable after several trips to Libertyville Toyota might mean that the dealer knew that fact, but it does not suggest that the dealer considered that fact to be a defect or knew that Plaintiff considered it to be one. Id. at 494, 590. Plaintiff's argument for applying the exception fails because she has not alleged that Libertyville Toyota, or any Defendant, was "apprised of the trouble with the particular product purchased by a particular buyer." Id. Thus, Count Four is dismissed.

# D. Unjust Enrichment (Count II)

\*6 Some Illinois courts have held that unjust enrichment is not a stand-alone cause of action. E.g. Martis v. Grinnell Mut. Reinsurance Co., 388 Ill.App.3d 1017, 1024–25, 329 Ill.Dec. 82, 905 N.E.2d 920, 928 (3d Dist.2009); Mulligan v. OVC, Inc., 382 Ill.App.3d 620, 631, 321 Ill.Dec. 257, 888 N.E.2d 1190, 1200 (1st Dist.2008). The Illinois Supreme Court's opinion in HPI Health Care Services, Inc. v. Mt. Vernon Hospital, Inc., 131 Ill.2d 145, 160, 137 Ill.Dec. 19, 545 N.E.2d 672, 679 (1989), however, appears to recognize unjust enrichment as a separate claim justifying recovery. See also Association Benefit Services, Inc. v. Caremark RX, Inc., 493 F.3d 841, 854 (7th Cir.2007) (treating unjust enrichment as standalone claim under Illinois law). In any event, recovery on an unjust enrichment theory requires allegations "that the defendant has unjustly retained a benefit to the plaintiff's detriment, and that defendant's retention of the benefit violates the fundamental principles of justice, equity, and good conscience." HPI Health Care Services,

131 III.2d at 160, 137 III.Dec. 19, 545 N.E.2d at 679. The only allegations in Plaintiff's complaint that might satisfy that requirement are those in support of her consumer fraud claim, but the court has already dismissed that claim. Moreover, unjust enrichment is a quasi-contract remedy available in equity; "damages for unjust enrichment are not awardable when, as here, there is a contract between the parties on the subject in dispute." *Prima Tek II, L.L.C. v. Klerk's Plastic Industries, B.V.,* 525 F.3d 533, 541 (7th Cir.2008) (applying Illinois law). Thus, Count Two is dismissed.

# E. Accounting (Count V)

To state a claim for the equitable relief of an accounting, Plaintiff must allege the absence of an adequate remedy at law and at least one of the following: "(1) a breach of a fiduciary relationship, (2) a need for discovery, (3) fraud, or (4) the existence of mutual accounts which are of a complex nature." Kempner Mobile Electronics, Inc. v. Southwestern Bell Mobile Systems, 428 F.3d 706, 715 (7th Cir.2005) (citing Mann v. Kemper Financial Cos., 247 Ill.App.3d 966, 980, 187 Ill.Dec. 726, 618 N.E.2d 317, 327 (1st Dist.1992)). Defendants argue, first, that Plaintiff has failed to allege the absence of an adequate remedy at law. (Defs' Br., at 9-10.) Plaintiff responds by reference to her complaint, which states, in an entirely conclusory manner, that she has no adequate remedy at law. (Compl., ¶ 51.B.) Merely reciting the elements of a claim is not sufficient to survive a motion to dismiss. Twombly, 550 U.S. at 555. Moreover, Plaintiff fails to explain why her contract claim is not an adequate remedy. There appears to be no reason that Plaintiff's damages will be difficult to measure, and the information that Plaintiff seeks will be available in discovery. Kempner, 428 F.3d at 715. Thus, Count Five is dismissed.

#### **CONCLUSION**

For the foregoing reasons, Defendants' Motion to Dismiss [13] is granted as to all claims except Plaintiff's claim of breach of contract against Defendant Libertyville Toyota. All dismissed claims are dismissed without prejudice. Plaintiffs has leave to file an amended complaint within 21 days. Whether or not Plaintiff chooses to re-allege the dismissed claims, the amended complaint must address the court's jurisdiction in light of the dismissal of the Defendants that are not Illinois citizens.

Case 1:19-md-02875-RMB-SAK Document 1451-1 Filed 08/02/21 Page 250 of 322 Sefton V. Toyota Motor Sales U.S.A., Not Reported 13 53 PRP 251 (2011)

2010 WL 1506709

**All Citations** 

Not Reported in F.Supp.2d, 2010 WL 1506709

**End of Document** 

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# Document 1451-1 PageID: 33313

# **Tab 28**

2004 WL 742033, 2004-1 Trade Cases P 74,415

2004 WL 742033 United States District Court, D. Minnesota.

SOLVAY PHARMACEUTICALS, INC., Plaintiff,

v.

ETHEX CORPORATION and KV Pharmaceutical Co., Defendants.

No. Civ. 03–2836 JRTFLN. | March 30, 2004.

# **Attorneys and Law Firms**

John B. Gordon and Peter J. Goss, Faegre & Benson LLP, Minneapolis, MN; and Saul H. Perloff, Akin Gump Strauss Hauer & Feld, LLP, San Antonio, TX, for plaintiff.

William Z. Pentelovitch, Maslon Edelman Borman & Brand, LLP, Minneapolis, MN; and Thomas C. Morrison and Robert W. Lehrburger, Patterson Belknap Webb & Tyler LLP, New York, NY, for defendants.

#### MEMORANDUM OPINION AND ORDER

# TUNHEIM, J.

\*1 Plaintiff Solvay Pharmaceuticals, Inc. ("Solvay") is a Georgia corporation with its principal place of business in Marietta, Georgia. Solvay has a manufacturing and packaging facility in Baudette, Minnesota. Defendants Ethex Corporation and KV Pharmaceutical Company (together "Ethex") are a Delaware corporation and a Missouri corporation, respectively, both having their principal places of business in St. Louis, Missouri. Both Solvay and Ethex produce and market competing prescription pancreatic enzyme supplements used in the treatment of cystic fibrosis. Solvay's products are marketed under the trademark Creon, while Ethex's products are marketed under the trademark Pangestyme. Specifically at issue in this case are Creon 10 and 20 and Pagnestyme CN–10 and CN–20.

Solvay contends that Ethex has falsely and misleadingly promoted and advertised Pangestyme CN-10 and CN-20 as substitutes for Creon 10 and 20. According to Solvay, Ethex markets the Pangestyme products either expressly or

by implication as "equivalent," "comparable," and "generic" versions of Creon, despite the fact that the two products are not, in fact, equivalent. Such false and misleading advertising and promotion has allegedly harmed Creon's sales and reputation, and puts cystic fibrosis patients at risk of receiving different treatment than that prescribed by their doctors.

Solvay alleges seven causes of action: (1) false advertising in violation of § 43(a) of the Lanham Act; (2) unfair competition in violation of § 43(a) of the Lanham Act; (3) violation of the Minnesota Unfair Trade Practices Act, Minn.Stat. § 325D.13; (4) violation of the Minnesota Uniform Deceptive Trade Practices Act, Minn.Stat. § 325D.44; (5) violation of the Minnesota False Advertising Act, Minn.Stat. § 325F.67; (6) violation of the Minnesota Consumer Fraud Act, Minn.Stat. § 325F.69; and (7) a request for declaratory judgment pursuant to 28 U.S.C. §§ 2201 and 2202 that Pangestyme CN–10 and CN–20 may not be lawfully substituted for Creon.

Ethex has filed a motion to dismiss all seven claims. Ethex objects that counts one through six are impermissible attempts to enforce the Federal Drug and Cosmetic Act ("FDCA"), which is only enforceable by the federal government. Ethex asserts that count seven should be dismissed because it requests relief against persons not party to the lawsuit, namely pharmacists and pharmacy boards who control substitution of drugs at the state level. Solvay responds that their claims are entirely based in advertising, and that any references to the Food and Drug Administration ("FDA") or FDCA are merely illustrative. Solvay also argues that the injunctive relief requested concerns Ethex's representations that ultimately lead to substitutions at the state level.

Solvay filed a nearly identical complaint against another drug company, which was assigned to and heard by United States District Judge Donovan W. Frank. The defendants' motion to dismiss in that case was granted in part and denied in part on January 9, 2004. See Solvay Pharmaceuticals, Inc. v. Global Pharmaceuticals, 298 F.Supp.2d 880, 2004 WL 62718 (D.Minn.2004).

Ethex has also filed a motion to transfer to the Eastern District of Missouri. Ethex contends that Solvay has very little connection to Minnesota, is trying to avoid an unfavorable forum, and would be no more inconvenienced by litigating in Missouri than they are by litigating in Minnesota. Conversely, Ethex claims to be very inconvenienced by litigating in Minnesota, and better able to handle the costs and inconvenience of litigation if this action were in Missouri.

#### DISCUSSION

#### I. STANDARD OF REVIEW

\*2 In a motion to dismiss, the Court construes the complaint in the light most favorable to the plaintiff and presumes all facts alleged in the complaint to be true. *Hishon v. King & Spalding*, 467 U.S. 69, 73, 104 S.Ct. 2229, 81 L.Ed.2d 59 (1984); *Schmedding v. Tnemec Co. Inc.*, 187 F.3d 862, 864 (8<sup>th</sup> Cir.1999). The Court may dismiss a claim only where the plaintiff cannot prove any set of facts in support of his claim that would entitle him to relief. *Conley v. Gibson*, 355 U.S. 41, 45–46, 78 S.Ct. 99, 2 L.Ed.2d 80 (1957); *Schmedding*, 187 F.3d at 864. The Court may grant a motion to dismiss on the basis of a dispositive issue of law, and may dismiss a claim founded upon a legal theory that is "close but ultimately unavailing." *Neitzke v. Williams*, 490 U.S. 319, 326–27, 109 S.Ct. 1827, 104 L.Ed.2d 338 (1989).

#### II. PREEMPTION OF CLAIMS 1-6

Ethex contends that Solvay's Lanham Act and state law claims concerning Ethex's marketing of Pangestyme as "equivalent," "substitutable," "generic," "comparable," or "alternative" to Creon imply that Ethex is improperly representing that Pangestyme is equivalent, as the FDA uses the term, to Creon. According to Ethex, whether the two drugs are equivalent is a matter properly left to the FDA, and it cannot be raised in a private right of action. Solvay maintains that it is alleging in this case that Creon and Pangestyme are factually not "equivalent," "substitutable," "generic," "comparable," and "alternative," and that Ethex's representations are therefore factually false. Solvay has specifically disclaimed any FDA related allegation.

#### A. The FDCA and FDA

The primary regulatory system covering prescription drugs was created by the Food, Drug and Cosmetic Act ("FDCA"). 21 U.S.C. § 301–92 (1982). The FDCA requires FDA approval, through a "new drug application" ("NDA"), before a new drug may be put on the market. *Id.* at §§ 331(d), 355(a). A product similar to an NDA approved drug may be approved and marketed based on an "abbreviated new drug application" ("ANDA"). *Id.* at § 355(j). An ANDA requires the manufacturer of the similar drug to demonstrate that the two drugs are therapeutically equivalent, that is pharmaceutically equivalent and bioequivalent. *Id.* at § 355(j)(2)(A)(i)-(viii). Each year the FDA publishes

Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the "Orange Book," listing all NDA approved drugs along with therapeutic equivalence determinations. Enforcement of the FDCA is permitted exclusively "by and in the name of the United States" or, in certain circumstances by a state. 21 U.S.C. § 337; see Sandoz Pharmaceuticals Corp. v. Richardson–Vicks, Inc., 902 F.2d 222, 231 (3<sup>rd</sup> Cir.1990) (FDA and FTC share exclusive jurisdiction over regulation of drug marketing requiring original interpretation of FDA or FTC acts or regulations).

- The FDA requires therapeutically equivalent products to be pharmaceutically equivalent and bioequivalent. See Introduction to Approved Drug Products with Therapeutic Equivalence Evaluations available at www.fda.gov/cder/ob.
- Two drugs sharing the same active ingredients, strength, and dosage are considered "pharmaceutically equivalent." 21 C.F.R. § 320.1(c); Introduction to Approved Drug Products with Therapeutic Equivalence Evaluations available at www.fda.gov/cder/ob.
- Two drugs that do not have significantly different rates and extent of absorption in the body are considered "bioequivalent." 21 U.S.C. § 355(j)(8)(B); 21 C.F.R. § 320.1(f); Introduction to Approved Drug Products with Therapeutic Equivalence Evaluations available at www.fda.gov/cder/ob.

Prescription pancreatic enzyme supplements are, like any other drug, subject to FDA regulation. In 1995 the FDA declared that all pancreatic enzyme drugs would require NDA or ANDA approval, but permitted such drugs to remain on the market while the FDA fleshed out the approval process. Thus, neither Creon nor Pangestyme has been tested, approved, compared or otherwise passed on by the FDA, and neither is listed in the Orange Book.

According to Ethex, the FDA may address the approval process for prescription pancreatic supplements this year.

#### B. The Lanham Act

\*3 The Lanham Act provides a private remedy to a plaintiff who has been harmed by "commercial advertising or promotion" that "misrepresents the nature, characteristics, qualities, or geographic origin of his or her or another person's goods, services, or commercial activities." 15 U.S.C. § 1125(a)(1)(B). The Act primarily protects commercial interests of individuals. *Sandoz*, 902 F.2d at 230. In contrast to the FDCA, the Lanham Act expressly establishes a private

right of action. See 15 U.S.C. § 1125(a). Ethex markets Pangestyme to doctors, pharmacists, drug wholesalers, and drug retailers.

#### C. Overlap

The FDCA and the Lanham Act overlap to the extent that both regulate drug products in the marketplace. Courts have recognized the potential conflict between the two Acts and have struggled to define the proper scope of each law. Courts have come to the general conclusion that the FDA's enforcement of the FDCA is primarily concerned with the safety and efficacy of new drugs, while the Lanham Act is focused on the truth or falsity of advertising claims. See, e.g., Sandoz, 902 F.2d at 230. More specifically, where a claim requires interpretation of a matter that is exclusively within the jurisdiction and expertise of the FDA and FDCA, plaintiffs cannot use the Lanham Act as a backdoor to private enforcement. Id. at 231; Mylan Laboratories, Inc. v. Matkari, 7 F.3d 1130, 1139 (4<sup>th</sup> Cir.1993). However, "false statements are actionable under the Lanham Act, even if their truth may be generally within the purview of the FDA," where the truth or falsity of the statements in question can be resolved through reference to standards other than those of the FDA. Summit Technology, Inc. v. High-Line Medical Instruments, 933 F.Supp. 918, 933 (C.D.Cal.1996).

Thus, the Fourth Circuit permitted a Lanham Act claim asserting that defendant Matkari's advertising statements that its drug was bioequivalent to Mylan's product was literally false. Mylan, 7 F.3d at 1138. Whether the tests cited by Matkari were falsified, unreliable, or non-existent and thus insufficient to support a claim of "bioequivalence" was a factual issue properly considered by the court. Similarly, in Sandoz Pharmaceuticals Corp. v. Richardson-Vicks, Inc., the court would have allowed a properly supported claim alleging that statements in an advertisement regarding a cough syrup's effectiveness were literally false or actually misleading to consumers. 902 F.2d 222, 227-29. In Grove Fresh Distributors, Inc. v. Flavor Fresh Foods, Inc., the existence of FDA regulations establishing a specific definition of the term "orange juice from concentrate" and prohibiting misbranding of food did not require dismissal of the Grove Fresh's claim that Flavor Fresh falsely described and misrepresented its product as "100% orange juice from concentrate." 720 F.Supp. 714, 715–16 (N.D.Ill.1989).

In contrast, the *Mylan* plaintiff's claim that defendant Vicks improperly implied FDA approval of its product was not

permitted under the Lanham Act because finding that the mere act of placing a drug on the market implied that the drug had been properly approved by the FDA would necessarily intrude on the FDA's exclusive right to grant, deny, or otherwise regulate such approval. *Id.* at 1139. The court in *Sandoz* declined to consider a Lanham Act false labeling claim that an ingredient listed as 'inactive' was required, under FDA standards, to be listed as 'active' because to do so would "require [the court] to usurp [the FDA's] responsibility for interpreting and enforcing potentially ambiguous regulations." *Sandoz*, at 231.

\*4 In Ethex Corporation v. First Horizon Pharmaceutical Corporation, on which Ethex relies, First Horizon alleged, in a counterclaim, that Ethex had violated the Lanham Act by marketing its prescription prenatal vitamins as a generic version of First Horizon's brand-name prescription prenatal vitamins. 228 F.Supp.2d 1048 (E.D.Mo.2002). First Horizon asserted that such a representation necessarily implied that the vitamins were therapeutically equivalent under the FDA standards. The Missouri court noted that "the touchstone of [First Horizon's] argument focuses on the fact that the word 'generic' implies FDA endorsement and certain FDA-defined concepts." The court dismissed the counterclaim because "the express language of [the] counterclaim" invoked FDA standards, and establishing those standards would therefore be impossible without FDA involvement.

Ethex contends that First Horizon is "virtually identical" to this case. The Court disagrees. Unlike the defendant/ counter-plaintiff in First Horizon, Solvay is not relying on either explicit or implicit FDA endorsement or terms that only the FDA can define. Solvay alleges that any statement or representation that Pangestyme is "equivalent," "substitutable," "generic," "comparable," and "alternative" to Creon is literally false. Similar to the plaintiff in *Grove Fresh*, Solvay may use the FDA regulations listing definitions of bioequivalence, pharmaceutical equivalence, and therapeutic equivalence to establish the appropriate standard by which to judge the literal falsity of Ethex's advertisements. See Grove Fresh, 720 F.Supp. at 716 (nothing prohibits a plaintiff from "rel[ying] on the FDA regulation merely to establish the standard or duty which defendants allegedly failed to meet."). However, "[e]ven without the FDA regulation ... [plaintiff] could attempt to establish a violation of section 43(a) .... [by] provid[ing] other evidence establishing the proper market definition" of generic, equivalent, comparable, or substitutable. Id. As Ethex acknowledges, an FDA

determination is not necessarily required in order for two drugs to be properly considered equivalent.

The Court is thus satisfied that Solvay could, based on the allegations in the complaint, prove that Pangestyme and Creon are not substitutable, alternatives, equivalent, or comparable, and that any advertisement to the contrary is literally false. Such a claim does not require the Court to determine anything within the particular jurisdiction of the FDA and is within the purview of the Lanham Act. Plaintiff's claims will therefore not be dismissed on this basis.

#### D. State law claims

The Minnesota Unfair Trade Practices Act, Uniform Deceptive Trade Practices Act, False Advertising Act, and Consumer Fraud Act are all designed to, among other things, protect individuals from false and misleading advertising. See Minn.Stat. § 325D.13 ("No person shall, in connection with the sale of merchandise, knowingly misrepresent, directly or indirectly, the true quality, ingredients or origin of such merchandise."); Minn.Stat. § 325D.44 ("A person engages in a deceptive trade practice when, in the course of business ... the person ... engages in any other conduct which similarly creates a likelihood of confusion or of misunderstanding."); Minn.Stat. § 325F.67 ("Any person, firm, corporation, or association who, with intent to sell or in anywise dispose of merchandise, ... makes, publishes, disseminates, circulates, or places before the public an advertisement of any sort ..., which advertisement contains any material assertion, representation, or statement of fact which is untrue, deceptive, or misleading, shall ... be guilty of a misdemeanor."); Minn.Stat. § 325F.69 ("The act, use, or employment by any person of any fraud, false pretense, false promise, misrepresentation, misleading statement or deceptive practice, with the intent that others rely thereon in connection with the sale of any merchandise ... is enjoinable.") Each permits an individual right of action. Minn. Stat. § 8.31, subd. 3a ("any person injured by a violation of [sections 325D.09 to 325D.16, other laws against false or fraudulent advertising, or sections 325F.68 to 325F.70] may bring a civil action ..."). Ethex asserts that Solvay's state law claims, like its Lanham Act claims, are improper attempts to privately enforce the FDCA. In light of the above analysis and discussion, the Court finds that Solvay's state law claims would not require the Court to infringe the FDA's authority and are therefore not improper.

III. STANDING—COUNTS 6 AND 7

#### A. Minnesota Consumer Fraud Act

\*5 The Minnesota Consumer Fraud Act, which prohibits the use of fraud, misrepresentation, or deceptive trade practices in connection with the sale of merchandise, was enacted to curb deceptive practices, including false or deceptive statements, in *consumer* transactions. Minn.Stat. § 325F.69, subd. 1; *Ly v. Nystrom*, 615 N.W.2d 302, 308 (Minn.2000) (emphasis added). As the manufacturer of a competing product, Solvay cannot be considered a consumer of Ethex's products and thus is not entitled to protection under the Minnesota Consumer Fraud Act. *See Kovatovich v. K–Mart Corp.*, 88 F.Supp.2d 975, 985 n. 4 (D.Minn.1999) (citations omitted). Solvay's Consumer Fraud Act claim is therefore dismissed.

#### B. Declaratory Relief

Whether one drug may be lawfully substituted for another is determined on a state-by-state basis. States fall into three general categories: those that permit substitution of prescription drugs based on an Orange Book determination of therapeutic equivalence, those that permit substitution based on any determination of therapeutic equivalence, and those that permit substitution based on a determination of pharmaceutical equivalence. Different states permit different entities-including individual pharmacists and boards of pharmacists—to determine which drugs meet the applicable state standard. Solvay requests a declaration from the Court that Pangestyme may not be substituted for Creon in Orange Book, Therapeutic Equivalence, or Pharmaceutical Equivalence states because Pangestyme is not listed in the Orange Book, is not therapeutically equivalent to Creon, and is not pharmaceutically equivalent to Creon. Solvay attempts to cast the claim as one directed at Ethex's marketing behavior. In other words, Solvay asserts that the requested injunction is necessary to prevent Ethex from continuing to market Pangestyme in such a way that pharmacists and pharmacist boards are led to believe that Pangestyme and Creon are essentially interchangeable.

The language of the Complaint, however, does not support Solvay's interpretation. If the requested injunction were to issue, and an individual pharmacist were nevertheless to substitute Pangestyme in filling a customer's prescription for Creon, that individual pharmacist, could be held responsible for the wrongful substitution. Ethex may or may not be implicated in any way. The requested injunction thus clearly reaches individual pharmacists and pharmacist boards, none of who are parties to this case. The Court is not empowered to issue relief against persons not party to the proceeding, who

have had no opportunity to participate in the decision. Further, such an injunction would conflict with the laws of states permitting substitution based on independent judgments of therapeutic or pharmaceutical equivalence, raising serious federalism concerns. Finally, if Solvay is able ultimately to prove that Pangestyme and Creon are not, in fact, "generic," "comparable," "substitutable" or "equivalent," Ethex will, effectively, not be able to market Pangestyme as any of those things. That outcome is essentially the relief that Solvay claims to seek. For all of these reasons, the Court will dismiss the claim for declaratory judgment in count 7.

#### IV. ETHEX'S MOTION TO TRANSFER VENUE

\*6 Ethex also moves to transfer venue to Missouri under 28 U.S.C. § 1404(a). To determine whether to transfer a case, the Court must consider: (1) the convenience of the parties; (2) the convenience of the witnesses; and (3) the interests of justice. Terra Int'l, Inc. v. Mississippi Chem. Corp., 119 F.3d 688, 691 (8<sup>th</sup> Cir.1997); Commodities Specialists Co. v. Brummet, 2002 WL 31898166 (D.Minn.2002). "The party seeking transfer bears the burden of proof to show that the balance of factors 'strongly' favors the movant." Id. (citation omitted); see also Martin v. Wal-Mart Stores, Inc., 2000 WL 33915814 at \*8 (N.D.Iowa October 9, 2000) (citing Kovatch v. Rockwood Sys. Corp., 666 F.Supp. 707, 708 (M.D.Pa.1986) ("Normally, plaintiff's choice of forum will not be disturbed unless the movant for transfer demonstrates that the balance of convenience and justice weighs heavily in favor of transfer.")).

Ethex argues that it is a smaller company than Solvay, and would therefore be more inconvenienced by having to litigate in Minnesota while running their business in Missouri than Solvay would be by having to litigate in the state of Missouri. While it may be true that Ethex is smaller than Solvay, Ethex is hardly the sort of small operation that would be seriously harmed by being required to devote resources to out-of-state litigation. To the contrary, Ethex seems to efficiently conduct a multi-million dollar business around the country. Further, transferring this litigation to Missouri would require any of Solvay's employees who reside in Minnesota to travel to Missouri to testify. Merely transferring the inconvenience from one party to the other is not an appropriate reason to transfer venue. *Graff v. Qwest Communications Corp.*, 33 F.Supp.2d 1117, 1121 (D.Minn.1999).

Ethex also argues that more potential witnesses reside in Missouri than Minnesota. The sheer number of witnesses,

however, is not necessarily dispositive. *See In re Warwick*, 70 F.3d 736, 741 (2<sup>nd</sup> Cir.1995). Instead, the Court's analysis focuses on "whether the forum ... is so inconvenient as to inhibit the access of one party or the other to necessary witnesses." *Terra Int'l Inc. v. Mississippi Chem. Corp.*, 922 F.Supp. 1334, 1360 (N.D.Iowa 1996), *aff'd*, 119 F.3d 688 (8<sup>th</sup> Cir.1997). Many of Ethex's potential witnesses are Ethex employees, and while traveling to Minnesota to testify may be somewhat inconvenient, the Court has little doubt that these witnesses will make themselves available. In addition, Ethex has offered no evidence of nonparty witnesses who are unwilling or unable to testify in Minnesota and has not argued that offering videotaped deposition testimony would be inadequate. There is no evidence before the Court that any nonparty witnesses would be beyond the reach of discovery.

In short, Ethex has failed to carry its burden of convincing the Court that transfer of venue is necessary and its motion is therefore denied.

## V. ETHEX'S MOTION TO FILE SUPPLEMENTAL AUTHORITY

\*7 Ethex requested permission from the Court to file supplemental authority consisting of the unpublished district court opinion on summary judgment in Florida Breckenridge, Inc. v. Solvay Pharmaceuticals, Inc., 1998 U.S. Dist. LEXIS 14742 (S.D.Fla. March 18, 1998). Ethex had previously cited the Eleventh Circuit's later opinion in the same case. Solvay objected to Ethex's request, arguing that supplemental authority should be limited to new authority, and that any supporting argument should be kept to a minimum. While the Court generally agrees with these principles, they do not require striking Ethex's supplemental authority in this instance. The additional submission is minimal. Further, Solvay had the opportunity to respond to the submission and, in light of the above analysis and decision, was not prejudiced by any consideration the Court may have given it. For these reasons, the Court grants Ethex's motion.

#### **ORDER**

Based on the foregoing, all the records, files, and proceedings herein, IT IS HEREBY ORDERED that:

1. Defendants' Motion for Judgment on the Pleadings [Docket No. 25] is GRANTED in part and DENIED in part.

- a. Defendants' motion is GRANTED as to counts 6 (Consumer Fraud Act) and 7 (declatory relief). Counts 6 and 7 of the Complaint [Docket No. 1] are DISMISSED with prejudice.
- b. Defendants' motion is DENIED in all other respects.
- 2. Defendants' Motion to Transfer Venue [Docket No. 15] is DENIED.

3. Defendants' Motion for Leave to File Supplemental Authority [Docket No. 31] is GRANTED.

#### **All Citations**

Not Reported in F.Supp.2d, 2004 WL 742033, 2004-1 Trade Cases P 74,415

**End of Document** 

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# **Tab 29**

KeyCite Yellow Flag - Negative Treatment
Declined to Follow by Lipstein v. United Healthcare Ins. Co., D.N.J.,
November 22, 2011

2009 WL 2905471
Only the Westlaw citation is currently available.
NOT FOR PUBLICATION
United States District Court, D. New Jersey.

Mary STALLINGS, Co-Executrix, and Patricia Stallings, Co-Executrix on Behalf of the ESTATE OF Viola STALLINGS, Plaintiffs,

v.

IBM CORPORATION, the Board of
Benefits and Pensions of the IBM
Disability Retirement and Sickness and
Accident Income and Benefits Plans,
R.A. Barnes, Metlife Insurance Co.,
and John Doe(s) 1-15, said name being
fictitious and unknown, jointly, severally,
and/or in the alternative, Defendants.

Civil No. 08-3121 (RBK/JS).

|
Docket Nos. 14, 15 & 22.

|
Sept. 8, 2009.

West KeySummary

## 1 Limitation of Actions ← Agreements as to Period of Limitation

Two year limitations period to state a claim for ERISA benefits was not manifestly unreasonable where the parties had contracted for such a period. The claimant was denied long term disability benefits as a result of a work-related automobile accident that caused severe injuries. The claimant subsequently passed away and the co-executrixes failed to bring a claim within the limitations period where two years provided sufficient opportunity for the claimant to state a

claim for benefits. Employee Retirement Income Security Act of 1974, § 502, 29 U.S.C.A. § 1132.

#### **Attorneys and Law Firms**

Richard E. Yaskin, Law Offices of Richard E. Yaskin, Cherry Hill, NJ, for Plaintiffs.

#### **OPINION**

KUGLER, District Judge.

\*1 This action arises out of decedent Dr. Viola Stallings' denied claim for disability benefits. Plaintiffs brought claims alleging violations of the Employee Retirement Insurance Security Act (ERISA), 29 U.S.C. § 1001 et. seq., and state law claims for unjust enrichment, breach of implied contract and covenant of good faith and fair dealing. Presently before the Court are a motion for summary judgment by Defendants IBM Corporation and R.A. Barnes (collectively IBM), <sup>1</sup> a motion to dismiss by Metlife Insurance Co. (Metlife).<sup>2</sup> and motions for partial summary judgment and to amend by Plaintiffs Mary and Patricia Stallings on behalf of the Estate of Viola Stallings. For the reasons set forth below, IBM's motion for summary judgment is GRANTED, Metlife's motion to dismiss is GRANTED, Plaintiffs' motion for summary judgment and motion to amend are DENIED, and the John Doe defendants are DISMISSED.

- Defendant IBM Corporation answered the Complaint denying that The Board of Benefits and Pensions of the IBM Accident Income and Benefits Plans exists as a separate entity. Answer at introduction, ¶ 7.
- Defendant Metlife Insurance Co. stated in its brief that its proper name is Metropolitan Life Insurance Company.

  Metlife br. at 1.

#### I. BACKGROUND

Dr. Viola Stallings, now deceased, began her employment at IBM Corporation on May 3, 1976, and continued to work there through 2002. In November 2001, Dr. Stallings sustained severe injuries in a work-related automobile accident. After the accident, Dr. Stallings suffered from various physical and psychological impairments and began working a reduced schedule in late 2001. Dr. Stallings

received medical care approximately every other week from Dr. Arthur Marks after the accident, voicing complaints of headaches, slurred speech, loss of concentration, and possible loss of consciousness.

On March 13, 2002, Dr. Marks recommended that Dr. Stallings take time off of work, which she promptly did. During her absence, Dr. Stallings continued to by paid by IBM either under unpaid leave or pursuant to IBM's Sickness and Accidents Benefits Plan (S & A Plan)-a short term disability plan. On April 10, Dr. Marks again evaluated Dr. Stalling and determined that she was unable to work "due to her psychological condition." Plaintiffs' br. at 2. Thereafter, on May 23, 2002, IBM contacted Dr. Stallings via latter to notify her that she was not certified for short term disability benefits and that she was on uncertified leave. The letter requested that Dr. Stallings provide additional documentation to support her short-term disability leave. On May 28, 2002, IBM also notified Dr. Stallings that she had been selected for an "outsource position elimination" effective June 30, 2002in other words, Dr. Stallings' job was terminated.

On June 20, 2002, Dr. Stallings was again evaluated by Dr. Marks, who noted that Dr. Stallings could return to work at least on a part-time basis. Meanwhile, Dr. Linda Rock, an IBM physician, spoke with Dr. Janice Cederstrom, Dr. Stallings' psychiatrist, and also reviewed the reports submitted by Dr. Stallings. Dr. Rock determined that no significant medical findings existed as to why she could not return to work.

Dr. Stallings was terminated on June 30, 2002 pursuant to the elimination plan and she received her entire salary and benefits through that date. At that time she was offered a severance package providing six month pay provided she sign a general release of claims. Dr. Stallings never signed the release.

\*2 On March 31, 2003, Dr. Stallings requested that IBM send her the plan documents for the plans in which she participated as an IBM employee. On June 12, 2003, IBM sent a letter to Dr. Stallings purportedly enclosing the requested documents. On July 11, 2003, Dr. Stallings contacted Metlife, the administrator of IBM's IBM Long Term Disability Policy (the LTD Plan), indicating that she intended to file a claim for benefits. On August 27, 2003, Metlife sent Dr. Stallings a letter informing her that she did not qualify for LTD benefits because she had not qualified for short term disability benefits for the requisite period of time.

On April 1, 2005, Dr. Stallings, through counsel, wrote a letter to IBM requesting retroactive short term disability benefits and long-term disability benefits. The letter included a conditional request that IBM supply relevant plan documents should Dr. Stallings' claims be denied. On April 29, 2005, IBM sent a letter to Dr. Stallings' counsel confirming receipt of the letter and the enclosed medical documentation, and inviting Dr. Stallings to submit additional medical evidence. Dr. Stallings supplemented her April 1, 2005 letter with additional documentation in May 2005. On October 10, 2005, IBM plan administrator Rosemarie "R.A." Barnes issued a letter to Dr. Stallings denying her short term disability claim. Unfortunately, Dr. Stallings died in November 2005 from a brain tumor.

One year later, on October 9, 2006, counsel for the estate of Dr. Stallings wrote IBM requesting that it reopen the October 2005 short term benefits decision. The letter requested that IBM provide counsel with the relevant plan documents. IBM responded on November 9, 2006, stating that IBM had reviewed the file and had found no reason to reopen the denial decision. The letter also supplied the requested plan documents.

On April 12, 2007, counsel for the Estate of Dr. Stallings again requested that IBM reopen its October 2005 decision, enclosing additional medical records with the request. IBM again denied the request on June 11, 2007.

Plaintiffs Mary and Patricia Stallings, co-executrixes of the Estate of Dr. Stallings, filed this action on June 23, 2008 on behalf of the Estate seeking LTD disability benefits under ERISA (Count One), alleging breach of fiduciary duty (Count Two), alleging failure to provide plan documents as required by ERISA (Count Three), and alleging unjust enrichment, breach of implied contract and covenant of good faith and fair dealing (Count Four). Defendants IBM and R.A. Barnes (collectively IBM) filed a motion for summary judgment under Federal Rule of Civil Procedure 56 as to all claims on February 10, 2009, and Defendant Metlife filed a motion to dismiss under Federal Rule of Civil Procedure 12(b)(6) on February 10th as well. Plaintiffs cross motioned for partial summary judgment and for leave to amend on April 1, 2009.

#### II. STANDARD

Summary judgment is appropriate where the court is satisfied that "there is no genuine issue as to any material fact and that the movant is entitled to judgment as a matter of law."

Fed.R.Civ.P. 56(c). A genuine issue of material fact exists "if the evidence is such that a reasonable jury could return a verdict for the nonmoving party." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248, 106 S.Ct. 2505, 91 L.Ed.2d 202 (1986). "In considering a motion for summary judgment, a district court may not make credibility determinations or engage in any weighing of the evidence; instead, the nonmoving party's evidence 'is to be believed and all justifiable inferences are to be drawn in his favor.' "*Marino v. Indus. Crating Co.*, 358 F.3d 241, 247 (3d Cir.2004) (quoting *Anderson*, 477 U.S. at 255).

\*3 "[T]he party moving for summary judgment under Fed.R.Civ.P. 56(c) bears the burden of demonstrating the absence of any genuine issues of material fact." *Aman v. Cort Furniture Rental Corp.*, 85 F.3d 1074, 1080 (3d Cir.1996). The moving party may satisfy its burden either by "produc[ing] evidence showing the absence of a genuine issue of material fact" or by "'showing'-that is, pointing out to the district court-that there is an absence of evidence to support the nonmoving party's case." *Celotex Corp. v. Catrett*, 477 U.S. 317, 325, 106 S.Ct. 2548, 91 L.Ed.2d 265 (1986). If the moving party satisfies its burden, the nonmoving party must respond by "set [ting] out specific facts showing a genuine issue for trial." Fed.R.Civ.P. 56(e)(2). "If the opposing party does not so respond, summary judgment should, if appropriate, be entered against that party." *Id*.

Alternatively, in reviewing a motion to dismiss under Federal Rule of Civil Procedure 12(b)(6), the court must accept Plaintiff's allegations, along with all reasonable inferences that may be drawn from them, as true. *Doe v. Delie*, 257 F.3d 309, 313 (3d Cir.2001) (citing *Piecknick v. Commonwealth of Pennsylvania*, 36 F.3d 1250, 1255 (3d Cir.1994)). The court may dismiss the complaint only if the plaintiff can prove no set of facts that would entitle him to relief. *Burstein v. Retirement Account Plan for Employees of Allegheny Health Educ. & Research Found.*, 334 F.3d 365, 374 (3d Cir.2003) (citation omitted). Nevertheless, factual allegations in the complaint "must be enough to raise a right to relief above the speculative level." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 545, 127 S.Ct. 1955, 167 L.Ed.2d 929 (2007).

#### III. ANALYSIS

A. Count I: LTD Benefits

#### 1. Statute of limitations

In Count One, Plaintiffs seek recovery of LTD Benefits under 29 U.S.C. § 1132, asserting that the Defendants reached an arbitrary and capricious decision. IBM and Metlife both present the same argument that Plaintiffs' claims for recovery of LTD benefits are time barred. The Defendants' motions come to the Court in different procedural postures: a motion for summary judgment and a motion to dismiss. For the purpose of clarity and because the conclusion to each motion is the same regardless of the posture, both arguments are discussed here as motions to dismiss and both motions are granted.

In considering a motion to dismiss, the court generally may not consider matters "extraneous to the pleadings." *In re Burlington Coat Factory Sec. Lit.*, 114 F.3d 1410, 1426 (3d Cir.1997). However, the court may consider a "'document *integral to or expressly relied* upon in the complaint' "without converting the motion to dismiss to a summary judgment motion. *Id.* (quoting *Shaw v. Digital Equip. Corp.*, 82 F.2d 1194, 1220 (1st Cir.1996)). Further, "a court may consider an undisputedly authentic document that a defendant attaches as an exhibit to a motion to dismiss if the plaintiff's claims are based on the document." *Pension Ben. Guar. Corp. v. White Consol. Industries*, 998 F.2d 1192, 1196 (3d Cir.1993).

\*4 The Complaint repeatedly makes reference to the IBM LTD Plan, *see*, *e.g.*, Compl. at ¶ 22, and is dependent on Dr. Stallings having been denied LTD benefits. However, the Plaintiffs did not attach any exhibits to the Complaint. Notwithstanding, the Court will consider both the actual language of the LTD Policy and Metlife's August 27, 2003 denial letter because both are integral to the Plaintiffs' claim and the denial letter in particular is "undisputedly authentic." *See* Plaintiffs' undisputed facts at ¶ 23 (acknowledging Metlife's letter).

#### a. Contractual limitations period

A person can bring a civil action under ERISA § 502(a) (1)(B), 29 U.S.C. § 1132(a)(1)(B), to recover benefits due. ERISA does not contain a statute of limitations for benefits claims under § 502(a)(1)(B). See Koert v. GE Group Life Assurance Co., 231 Fed. Appx. 117, 119 (3d Cir.2007). Courts generally, therefore, borrow the limitations period for the most analogous state cause of action. Id. (citing Gluck v. Unisys Corp., 960 F.2d 1168, 1179 (3d Cir.1992)). The most analogous claim for a benefits claim is breach of contract, which in New Jersey carries a six year limitations period. Klimowicz v. Unum Life Ins. Co. of Am., 296 Fed. Appx. 248, 250 (3d Cir.2008). However, the parties to a benefits plan may

contract for a shorter limitations period provided the supplied period is not "manifestly unreasonable." Id.; Koert, 231 Fed. Appx. at 120. The Third Circuit has not expressly stated what makes a contractual period unreasonable in the ERISA context, but has found as little as a three year limitations period reasonable. See Klimowicz, 296 Fed. Appx. at 251; Koert, 231 Fed. Appx. at 120; Fontana v. Diversified Group Adm'rs, Inc., 67 Fed. Appx. 722, 724 n. 1 (3d Cir.2003); see also Grasselino v. First Unum Life Ins. Co., No. 08-cv-635, 2008 WL 5416403, at \*3 (D.N.J. Dec.22, 2008). Other courts have found anywhere from 90 days, to 12 months, to 2 years and 90 days to be reasonable limitations periods. See Northlake Reg'l Med. Ctr. v. Waffle House Sys. Employee Benefit Plan, 160 F.3d 1301, 1304 (11th Cir. 1998) (upholding 90 days); Payne v. Blue Cross & Blue Shield, 976 F.2d 727 (Table), 1992 WL 235537, at \*2 (4th Cir.1992) (upholding 12 months); Scheirer v. NMU Pension & Welfare Plan, 585 F.Supp. 76, 78 (S.D.N.Y.1984) (upholding 2 years and 90 days).

As an initial matter, against whom and under what grounds Plaintiffs seek recovery of LTD benefits is unclear. For example, in Count One, Plaintiffs have captioned the claim as " 'Recovery of LTD Disability Retirement Benefits Due Pursuant to 29 U.S.C. § 1132.' "However, in the prayer for relief under Count One, Plaintiffs only demand judgment against Defendants IBM's Board of Benefits and Pensions, R.A. Barnes, and John Doe(s), Compl. at ¶ 53, but not Metlifewho seemingly has the sole ability to provide the relief. Id. at ¶ 9 ("Metlife was at all times from May 8, 2002 an ERISA fiduciary and the adjudicator of benefit entitlement under the IBM Long Term Disability Benefits plan."). Adding to the confusion, in Count Two, Plaintiffs captioned the claim as "Breach of Fiduciary Duty' vs. IBM Corp., Board of Benefits and Pensions, R.A. Barnes and John Doe(s)"; however, in the prayer for relief, Plaintiffs demand judgment against those parties and Metlife. Compl. at ¶ 61. Count Two is especially confusing because at no point in the Complaint do Plaintiffs allege that Metlife breached a fiduciary duty, rather the breach allegations are aimed at the IBM Defendants.

\*5 Notwithstanding the ambiguous pleadings, the substance of the benefits recovery claim appears to be a claim for relief under 29 U.S.C. § 1132(a)(1)(B), and because all parties have responded as if Plaintiffs were seeking recovery of benefits under that provision, the Court will analyze the motions as such. *See* Plaintiffs' br. at 15 ("New Jersey's six year statute of limitations for breach of contract claims governs Plaintiffs' LTD benefits claims under ERISA."); Metlife br. at 1 ("The

only relief sought in the Complaint as against Metlife is a rehearing of Stallings' claim for long term disability benefits pursuant to the terms of the IBM Long-Term Disability Plan. The Plaintiffs also seek additional relief from [IBM] in the form of 'long term disability retirement benefits' pursuant to [ERISA] ...."); IBM SJ br. at 1 ("Plaintiffs Mary and Patricia Stallings have brought this action on behalf of the Estate of Viola Stallings ... alleging that IBM and/or its long-term disability plan administrator, [Metlife] wrongfully denied Stallings (sic) long-term disability benefits pursuant to 29 U.S.C. § 1132 ....").

The Court's review of the limitations claims is twofold: 1) whether the limitations period in the LTD Plan applies, and if so, 2) when did Plaintiffs' claim under the LTD Plan accrue.

#### b. Application of the LTD Plan's limitations period

As discussed, parties may be bound by a shorter limitations period if they agreed to a period that is not "manifestly unreasonable." *See Klimowicz*, 296 Fed. Appx. at 250. Plaintiffs first challenge the LTD Plan's limitations period by claiming that Dr. Stallings never assented to the two year period. Plaintiffs' br. at 16. Plaintiffs' direct the Court's attention to a non-ERISA case applying Pennsylvania state law as authority for the proposition that a person can accept benefits of an ERISA plan without being bound by the plan's detriments. *See* Plaintiffs' br. at 16 (citing *Kirleis v. Dickie, McCamey & Chilcota, P.C.,* 560 F.3d 156 (3d Cir.2009)). *Kirleis* decided whether a partner at a law firm was bound by an arbitration provision in the firm's bylaws where the partner claimed to have never seen or agreed to the provision. 560 F.3d at 159-60.

The Plaintiffs' reliance on Kirleis is misplaced and their lack of assent argument must fail. Kirleis's holding regarding Pennsylvania contract law is certainly not applicable where the dispute is over an ERISA plan that is heavily regulated under federal law and the where the disputed provision is just one of many in a single plan under which the Plaintiffs seek recovery. Instead, the Court agrees with the logic used in Scheirer v. NMU Pension & Welfare Plan, 585 F.Supp. 76, 79 (S.D.N.Y.1984), an ERISA case, wherein the court reasoned "it would be anomalous for this Court to allow plaintiff to maintain an action to recover a benefit which was created by and exists solely because of the regulations of the [ERISA plan], while at the same time to deny effect to the conditions those same regulations place upon receipt of that benefit." Thus, Plaintiffs' challenge that Dr. Stallings did not agree to the LTD Plan's limitations period fails.

\*6 Plaintiffs second challenge to the LTD Plan's limitations period is that it is unreasonable because it is only one third of New Jersey's six year breach of contract limitations period. See Plaintiffs' br. at 15. This challenge is unpersuasive. Plaintiffs have not directed the Court's attention to any case holding that two years is unreasonable or that the proper touchstone for the reasonableness of a limitations period is a comparison to the venue state's limitations period. In the absence of such authority, the Court holds that nothing about the two year limitations period is "manifestly unreasonable" because the period provided sufficient opportunity for the Plaintiffs to state a claim for benefits, the two year period is not substantially different from previously upheld three year periods, see, e.g., Klimowicz, 296 Fed. Appx. at 251, and the period does interfere with Congress's intent to protect ERISA beneficiaries and participants. See generally 29 U.S.C. § 1001 (Congressional findings and declaration of policy).

Plaintiffs' third challenge to the limitations period is that even if it should otherwise apply, the Defendants are barred from enforcing it by equitable estoppel and waiver. See Plaintiffs' br. at 17. These defenses are easily rejected. For an equitable estoppel claim, the party asserting it must show three elements: "1) a material representation, 2) reasonable and detrimental reliance upon the representation, and 3) extraordinary circumstances ." Curcio v. John Hancock Mut. Life. Ins. Co., 33 F.3d 226, 235 (3d Cir.1994). What constitutes extraordinary circumstances is a case-specific inquiry, see id. at 237, but generally it involves acts of bad faith. Jordon v. Fed. Express Corp., 116 F.3d 1005, 1011 (3d Cir.1997). A waiver claim, on the other hand, requires that the asserting party show that the opponent intentionally relinquished or abandoned "a known right or privilege." Johnson v. Zerbst, 304 U.S. 458, 464, 58 S.Ct. 1019, 82 L.Ed. 1461 (1938).

Plaintiff's memorandum of law generally lumps waiver and estoppel together without directing the Court's attention to which factual allegations attach to which equitable defense and without directing the Court's attention to the predicate elements. On the issue of estoppel, Plaintiffs' seemingly assert that estoppel applies because no defendant promptly (if ever) alerted Dr. Stallings to her right to appeal or the process for her appeal, and also because IBM in particular "misdirected" Dr. Stallings by allowing her to submit additional medical evidence. *See* Plaintiffs' br. at 17-19.<sup>3</sup> These allegations are insufficient to state an estoppel defense. As to the lack of notice of an appeal right, that deficiency is considerably

less than a representation of fact upon which Dr. Stallings detrimentally relied. If Dr. Stallings had no notice of her right to appeal, that lack of notice was not a representation that no right existed. Moreover, even if lack of notice were a representation, it did not pose extraordinary circumstances sufficient to avoid the application of the LTD Plan's limitations period. See Grasselino, 2008 WL 5416403, at \*6 (holding plan's limitations period not tolled where defendant failed to notify plaintiff of right to appeal). Likewise, as to the assertion that IBM allowing Dr. Stallings to submit additional evidence for review estops the Defendants from asserting the contractual limitations period, that claim likewise fails to pose extraordinary circumstances. See O'Donnell v. Metro. Life Ins. Co., No. 08-cv-1117, 2009 WL 884699, at \*3 (S.D.N.Y. Feb.20, 2009) (discussing IBM's LTD Plan and holding that plaintiff's claim for relief accrued even though Metlife allegedly continued to review plaintiff's claim), report and recommendation adopted, 2009 WL 884811 (S.D.N.Y. Mar.31, 2009). Thus, Plaintiffs' estoppel defense to the limitations period fails.

- Plaintiffs' electronically filed memorandum of law, Docket No. 22, contains two page 18's. The difference between the two is slight and the Plaintiffs'argument is otherwise cohesive on the papers filed.
- \*7 On the issue of waiver, Plaintiffs' defense also fails. Relying on the same general factual allegations (that no Defendant timely informed Dr. Stallings (if ever) of her right to appeal and that IBM misdirected Dr. Stallings), nothing in Plaintiffs' argument suggests that any of the Defendants abandoned a known right. Read charitably, the Plaintiffs' factual allegations show a breach of duty but not a waiver of a right. Moreover, even if any of the Defendants' actions could be interpreted to show a waiver, ERISA precludes any modification of a covered plan-to the party's detriment or benefit-without a writing. See Hozier v. Midwest Fasteners, Inc., 908 F.2d 1155, 1163 (3d Cir.1990). No written waiver is alleged to exist here. Thus, the Plaintiffs' waiver defense to the limitations period fails.

Therefore, given that the Plaintiffs have no legitimate defenses to the LTD Plan's limitations period, and given that the clause is otherwise reasonable, Plaintiffs' claim for LTD benefits must be analyzed using a two year limitations period. The inquiry must then turn to when Plaintiffs' claim accrued.

#### c. Accrual

The Third Circuit applies the "discovery rule" to determine when a cause of action arises for statute of limitations purposes. Miller v. Fortis Benefits Ins. Co., 475 F.3d 516, 520 (3d Cir.2007). "In the ERISA context, the discovery rule has been 'developed' into the more specific 'clear repudiation' rule whereby a non-fiduciary cause of action accrues when a claim for benefits has been denied." Id. The clear repudiation rule does not require a formal denial or even a formal application, rather the rule only requires a "clear" repudiation that is made known to the plaintiff. Id. at 521. A limitations period is not tolled under ERISA where the defendant fails to inform the plaintiff of his right to appeal, provided the plaintiff receives clear notice that his right to benefits is being denied.<sup>4</sup> See Grasselino v. First Unum Life. Ins. Co., No. 08-cv-635, 2008 WL 5416403, at \*6 (D.N.J. Dec.22, 2008) (citing *Miller*, 475 F.3d at 521-23; Klimowicz, 2008 WL 4531958).

The right to appeal is significant in the ERISA context because regulations require that the participant or beneficiary be provided appeal information and the applicable time period following "an adverse determination on review." 29 C.F.R. § 2560.503-1(g)(iv). However, the remedy for violation of this regulation is a right to relief under § 502(a) of ERISA for failure to provide a reasonable claims procedure. § 2560.503-1(l).

Plaintiffs argue on two fronts that their claim for benefits never accrued: 1) Dr. Stallings never submitted a written application or submitted proof of injury to Metlife, and 2) allowing a claim to accrue absent proof of injury would lead to unpredictable application of ERISA limitations periods. Plaintiffs' br. at 16, 19. Plaintiffs' first defense is based on language in the LTD Plan that states "no legal action may be started to obtain legal benefits until 60 days after proof is given." Id. (emphasis added). Plaintiffs submit that Dr. Stallings never submitted any proof, thus the limitations period never began. However, the LTD Plan also states "Proof of ... injury or sickness should, if possible, be provided to Metropolitan within 90 days after the date you would be first entitled to receive Long-Term Disability benefits. In no case should this proof be provided any later than 12 months after the date you would be entitled to first receive Long-Term disability benefits." Metlife br. at Ex. A at Metlife0035 (LTD Plan) (emphasis added). On the basis of this last provision, Plaintiffs cannot defensibly argue that Dr. Stallings controlled the accrual of her claim under the terms of the LTD Plan. The LTD Plan clearly limits the time within which a participant must file a claim. A conclusion that Dr. Stallings controlled when her claim accrued would lead to an

"indefinite limitations period," which the Third Circuit has definitively foreclosed. *See Miller*, 475 F.3d at 522.

\*8 Plaintiffs second defense is easily dispatched. Plaintiffs rely on *White v. Sunlife Assurance Co. of Canada*, 488 F.3d 240, 247-53 (4th Cir.2007), for the proposition that accrual absent a claim of proof would lead to unpredictability in ERISA regulation. *See* Plaintiffs' br. at 16. Whatever merit *White* may have in its reasoning, it has no bearing here. The Fourth Circuit in *White* used an accrual test based on a formal denial, 488 F.3d at 246, which is directly contrary to the Third Circuit's test in *Miller*. Thus, the Court cannot be bound by *White's* reasoning or Plaintiffs' argument thereunder.

Therefore, applying the clear repudiation rule, Dr. Stallings' claim accrued approximately on August 27, 2003 when she received the letter from Metlife denying her claim for LTD benefits. The letter stated: "Since you did not complete the waiting period as defined above, you are not eligible for Long Term Disability. Therefore your long term Disability Claim is denied." Metlife br. at Ex. B. This language is clear evidence that Metlife was repudiating any claim Dr. Stallings had to benefits, and the letter clearly communicated that to her. Even though the denial letter had no directions on how to appeal, the letter still clearly repudiated Dr. Stallings' claim. Thus, the limitations period on Dr. Stallings' claim began in August 2003 and expired two years later in August 2005. Because Plaintiffs did not file suit until June 23, 2008, Docket No. 1, Plaintiffs claims for LTD benefits are untimely. Metlife's motion to dismiss is therefore granted and IBM's motion for summary judgment is granted as to Count One.<sup>5</sup>

Because the Court grants Defendants' motions on the limitations defense, analysis of Plaintiffs' "conflict of interest" standard of review claim in Count I is moot.

#### 2. Plan administrator

But for the limitations defense above, summary judgment would also be proper on Count One for IBM because IBM was not the LTD Plan administrator. IBM asserts that at all times Metlife was the LTD Plan administrator. IBM asserts that under the LTD Plan, participants were to submit all claims for LTD benefits to Metlife and Metlife alone had discretion to grant or deny the claims. IBM SJ br. at 13 (citing Ex. W at IBM01302 (the LTD Plan)). IBM further asserts that the Plaintiffs admit that Metlife was the decision-maker with respect to the LTD Plan. *See id.;* Compl. at ¶ 9 ("Metlife was at all times from May 8, 2002 an ERISA fiduciary and the adjudicator of benefit entitlement under

the IBM Long Term Disability Benefits Plan."). IBM then concludes that Plaintiffs' claim for recovery of LTD benefits should be dismissed because Metlife made the decision with regard to LTD benefits, Dr. Stallings never submitted a claim to IBM for LTD benefits, and because IBM had no input on the decision.

Plaintiffs seemingly offer no response, factual or legal, to IBM's defense. Plaintiffs agree that Dr. Stallings intended to file a claim with Metlife for LTD benefits in July 2003, and Plaintiffs agree that Metlife determined eligibility for LTD benefits in its discretion. Plaintiffs' undisputed facts at ¶¶ 22, 42. On the basis of these facts and admissions, the Court is inclined to agree that the IBM Defendants' motion for summary judgment should be granted as to Count I. However, because the law and factual allegations are well developed as to IBM's limitations defense as discussed above, the Court grants summary judgment on the limitations defense.

### B. Count Two: Breach of Fiduciary Duty<sup>6</sup>

- To the extent Plaintiffs claim breach of fiduciary duty against Metlife under Count Two, that claim fails and is dismissed because Plaintiffs failed to allege any facts showing a breach by Metlife. See Compl. at ¶ 61(a)-(g); Plaintiffs' br. at 20 (caption to "Point V" only alleges that IBM and Rosemarie Barnes breached a fiduciary duty).
- \*9 Defendant IBM makes two preliminary challenges to Count Two that are quickly disposed of. First, IBM asserts that Plaintiffs' breach of fiduciary duty claim is pre-empted. See IBM SJ br. at 20. To the extent that Plaintiffs are asserting a state law claim in Count Two, the claim is pre-empted for the reasons discussed *infra*. However, Plaintiffs have responded as if the claim is for relief under ERISA and the Court will respond as such. Thus, IBM's pre-emption challenge fails.

Second, IBM asserts that Plaintiffs' claim for disability benefits in Count Two is time barred for the same reasons as discussed above. *See* IBM SJ br. at 9 n. 5. Because IBM has provided little support for this argument as applied to Count Two and because the Court otherwise finds that Plaintiffs' breach of fiduciary duty claim is improper, IBM's limitations period challenge fails as well.

#### 1. ERISA § 502(a)(2)

Plaintiffs' breach of fiduciary duty claim in Count Two is based on ERISA § 502(a)(2), 29 U.S.C. § 1132(a)(2), and § 502(a)(3), 29 U.S.C. § 1132(a)(3). See Plaintiffs' br.

at 20. Section 502(a)(2) enables civil suits for violations of § 409 of ERISA, 29 U.S.C. § 1109, which outlines liability for breach of fiduciary duty to a plan. Recovery under § 502(a)(2) "inures to the benefit of the plan as a whole," Massachusetts Mut. Life Ins. Co. v. Russell, 473 U.S. 134, 140, 105 S.Ct. 3085, 87 L.Ed.2d 96 (1985), meaning individuals generally cannot recover personal damages for a breach of fiduciary duty. Precopio v. Bankers Life & Cas. Co., No. 01-cv-5721, 2004 WL 5284512, at \*28-29 (D.N.J. Aug. 10, 2004). However, the Supreme Court recently announced a limited exception to this rule, holding that in defined contribution plans (versus defined benefits plans) an individual can recover under § 502(a)(2) for breaches of fiduciary duty that caused the individual's personal account to lose value. LaRue v. DeWolff, Boberg & Assocs., Inc., 552 U.S. 248, ----, 128 S.Ct. 1020, 1025, 169 L.Ed.2d 847 (2008).

Plaintiffs' only seek personal recovery of LTD benefits purportedly due to Dr. Stallings and do not seek derivative recovery for the LTD Plan itself. See Compl. at 15. Plaintiffs argue that suit under § 502(a)(2) is appropriate because LaRue eroded the rule announced in Russell and now permits individual recovery for breach of fiduciary duty. See Plaintiffs' br. at 20. Plaintiffs' argument misunderstands the limited nature of LaRue and therefore fails.

LaRue itself clearly limits its holding to defined contribution plans, 128 S.Ct. at 1025, which are not at stake here. Every court to review LaRue outside of the defined contribution plan context has held that individual recovery for breach of fiduciary duty is barred. See, e.g., Rosenblatt v. United Way of Greater Houston, 590 F.Supp.2d 863, 876 (S.D.Tex.2008); Estate of Spinner v. Anthem Health Plans of Virginia, 589 F.Supp.2d 738, 746 (W.D.Va.2008); Fenwick v. Merrill Lynch & Co., Inc., 570 F.Supp.2d 366, 375 (D.Conn.2008). Therefore, the Court grants IBM summary judgment as to Plaintiffs' claim under Count Two for breach of fiduciary duty under § 502(a)(2).

#### 2. ERISA § 502(a)(3)

\*10 Plaintiffs also seek recovery in Count Two under ERISA § 502(a) (3), 29 U.S.C. § 1132(a)(3). See Plaintiffs' br. at 20. Section 502(a)(3) is a civil enforcement "catch all" that provides equitable relief for injuries not remedied elsewhere in § 502. Varity Corp. v. Howe, 516 U.S. 489, 512, 116 S.Ct. 1065, 134 L.Ed.2d 130 (1996). Unlike § 502(a)(2), § 502(a)(3) permits individual relief. Id. at 511; Bixler v. Central Pennsylvania Teamsters Health & Welfare Fund, 12 F.3d 1292, 1299 (3d Cir.1993). Notwithstanding, § 502(a)(3)

has its limits. First, the section only provides equitable relief, meaning only relief that was traditionally available in courts of equity. *Great-West Life & Annuity Ins. Co. v. Knudson*, 534 U.S. 204, 209-10, 122 S.Ct. 708, 151 L.Ed.2d 635 (2002). Second, the section only applies where the participant or beneficiary is seeking a remedy that is not otherwise recoverable under § 502. *Precopio*, 2004 WL 5284512, at \*31 (citing *Varity*, 516 U.S. at 515; *Ream v. Frey*, 107 F.3d 147, 152 (3d Cir.1997)). This second limitation does not mean that the party must have a *successful* claim elsewhere under § 502, rather the party must not even have a *potential* claim. *Id.* (citing *Tolson v. Avondale Ind., Inc.*, 141 F.3d 604, 610-11 (5th Cir.1998)); *Estate of Spinner*, 589 F.Supp.2d at 746.

Under these standards, Plaintiffs claims for relief under § 502(a)(3) fails. First, Plaintiffs are seeking legal and not equitable relief. Plaintiffs' requests in Count Two mostly seek recovery of money purportedly due and owing to the late Dr. Stallings. Plaintiffs couch their claim as one for "restitution," but placing an equitable moniker on the relief sought does not automatically convert the relief into equitable relief. See Great-West, 534 U.S. at 212 (holding "not all relief falling under the rubric of restitution is available in equity"). Purported restitution that seeks only payment of funds owed rather than a recovery of funds to which the party once had rightful title is "'quintessentially an action at law.' " Id. at 210, 213 (quoting Wal-Mart Stores, Inc. v. Wells, 213 F.3d 398, 401 (7th Cir.2000)). Plaintiffs' claims here are exactly that-an action at law. Dr. Stallings never had title to the funds and only claimed to have a contractual right to them. Therefore, relief in Count Two for her LTD benefits fails.

The remainder of the relief Plaintiffs seek in Count Two also fails because the Plaintiffs otherwise have a remedy under § 502-albeit an unsuccessful one. As sought in Plaintiffs' Count One and as discussed at length above, Plaintiffs' have a viable claim under § 502(a)(1)(B), 29 U.S.C. § 1132(a)(1)(B). Merely because Plaintiffs' claim fails on a limitations defense does not mean that they are now entitled to seek relief under ERISA's catch all provision. Stated differently, Plaintiffs had viable grounds to seek recovery for any fiduciary breach by IBM that caused them injury under § 502(a)(1)(B), but Dr. Stallings and now her Estate missed the period in which to file a claim. Thus, relief under § 502(a)(3) is inappropriate because Plaintiffs' alleged injuries were otherwise remediable under another provision.

\*11 Defendant IBM is therefore granted summary judgment as to Count Two. <sup>7</sup>

As noted above "IBM" means IBM Corporation and R.A. Barnes. Plaintiffs and Defendants each separately briefed the issue of Ms. Barnes' individual liability, but because Plaintiffs' claims in Count Two are otherwise defective, that issue is moot and summary judgment is granted to IBM Corporation and R.A. Barnes.

#### C. Count Three

In Count Three, Plaintiffs seek recovery for IBM's failure to provide requested information as required under ERISA § 104(b)(4), 29 U.S.C. § 1024(b)(4), and enforceable under ERISA § 502(c), 29 U.S.C. § 1132(c)(1). Plaintiffs have moved for partial summary judgment on this claim. Plaintiffs' claim fails because the purported "request" was not a request under ERISA and even if it were, a penalty would not otherwise be appropriate.

Section 104(b) (4) of ERISA provides that an "administrator shall, upon written request of any participant or beneficiary, furnish a copy of the latest updated summary[ ] plan description, and the latest annual report, any terminal report, the bargaining agreement, trust agreement, contract or other instruments under which the plan is established or operated." § 1024(b)(4). A breach of this provision is actionable under § 502(c)(1), which after 30 days permits a participant or beneficiary to recover a statutory penalty for each day the requested information is not provided. § 1132(c)(1).8 The purpose behind § 502(c)(1) is to "induce plan administrators to comply with ERISA's disclosure provisions, and not to make a participant whole." Maiuro v. Federal Express Corp., 843 F.Supp. 935, 943 (D.N.J.1994) (citing Groves v. Modified Retirement Plan for Hourly Paid Employees of the Johns Mansville Corp., 803 F.2d 109, 117 (3d Cir.1986)).

As enacted, § 502(c) only provides for a \$100 per day penalty; however, the penalty has been increased to \$110 per day by regulation. 29 C.F.R. § 2575.502c-1.

Section 502(c)(1) is a penal statute and as such is "narrowly construed." *Groves*, 803 F.2d at 118. This means that the terms of the statute are strictly defined, *see Haberern v. Kaupp Vascular Surgeons Ltd. Defined Benefit Pension Plan*, 24 F.3d 1491, 1505 (3d Cir.1994), and a plaintiff seeking damages under the statue must show compliance with the "statutory prerequisites." *Porcellini v. Strassheim Printing Co., Inc.,* 578 F.Supp. 605, 611 (E.D.Pa.1983). In this dispute, Plaintiffs must therefore show that there was "written request" for plan information, IBM failed to comply with the request, and a monetary penalty is warranted. *See* § 1132(c)(1).

#### 1. Written request

What constitutes a written "request" is not defined under § 502(c). See Haberern, 24 F.3d at 1505-06. The Third Circuit has seemingly held that a request must at least contain an actual demand for the plan documents. Id. at 1505-06 (holding letter from attorney requesting meeting and stating that certain materials "had not been supplied" was not a request). The Court also recently announced that a "clear notice test" test should be applied to requests, meaning the purported request is only sufficient if a reasonable administrator knew or should have known that the plaintiff requested plan documents. See Kollman v. Hewitt Assocs., LLC., 487 F.3d 139, 144, 145 (3d Cir.2007); see also Fisher v. Metro. Life Ins. Co., 895 F.2d 1073, 1077 (5th Cir.1990) (holding handwritten note requesting "policies covering my contract for salary continuation" not a request because no evidence to show that administrator "knew or should have known that [plaintiff] had requested a copy of any documents relating to the [plan]"); Moothart v. Bell, 21 F.3d 1499, 1504 (10th Cir.1994) (holding plaintiff made request for plan documents where requests were not "equivocal").

\*12 In this dispute, at least three purported requests are shown-only one of which is at issue. The first request occurred on March 31, 2003, when Dr. Stallings requested that IBM send her plan documents for the plans in which she participated as an IBM employee. Plaintiffs' undisputed facts at ¶ 20. IBM claims to have responded to this request with the appropriate documents on two occasions: May 5, 2003 and June 12, 2003. See IBM SJ reply br. at 6, Ex. A (May 5, 2003 response)<sup>9</sup>; Plaintiffs' undisputed facts at ¶ 21 (June 12, 2003 response). ID IBM's response or failure to respond to the March 31, 2003 request is not in issue.

- This purported disclosure was not stated in IBM's statement of material facts and arises in the papers for the first time in IBM's reply brief. Plaintiffs did not address this purported disclosure and thus the Court treats it as a disputed fact.
- Notably Plaintiffs acknowledge the text of IBM's letter that states the relevant documents are enclosed, but Plaintiffs do not acknowledge that the documents were actually enclosed.

Dr. Stallings' purported second request occurred when Dr. Stallings' counsel sent a letter to IBM on April 1, 2005 seeking retroactive benefits. That letter contained the following

language: "Should this request for Disability Retirement benefits not be immediately granted, I request copies of all IBM policies, Employee Benefit plans, summary IBM plan descriptions and other documents explaining the eligibility criteria for IBM Disability Retirement benefits effective as of March 2002." IBM SJ br. at Ex. L; Plaintiffs' undisputed facts at ¶ 24. Dr. Stallings' counsel acknowledged that this purported request was a "conditional request." IBM SJ br. at Ex. R (letter from counsel to IBM dated October 9, 2006: "I remain unable to quote the specific Plan provisions since my April 1, 2005 conditional request for copies of all IBM policies, employee benefit plans, summary plan descriptions and other documents ... has not yet been granted."). Six months later, on October 10, 2005, IBM informed Dr. Stallings that her April 1, 2005 request for retroactive benefits was denied. Plaintiffs' undisputed facts at ¶ 29. IBM did not, however, provide any plan documents with the denial, but did state the following: "If you would like a copy of the Summary Plan Description or any other information relevant to this claim, please contact the Employee Services Center at 1-800-796-9876." IBM SJ br. at Ex. Q; Plaintiffs' undisputed facts at ¶ 29.

Dr. Stallings' third purported request occurred on October 9, 2006 when her counsel again requested that IBM grant retroactive benefits. Plaintiffs' undisputed facts at ¶ 31. IBM sent the relevant plan documents on November 9, 2006. *Id.* at ¶ 33; Plaintiffs' br. at 17 ("[IBM] also failed to provide counsel the requested governing IBM benefits Plan documents for at least 18 months until November 9, 2006."). This third purported request is also not in dispute.

Based on the tests discussed above, the Court holds that Dr. Stallings' second purported request was not a statutory request under ERISA and she is therefore not entitled to relief. Plaintiffs do not dispute that the April 1 letter was a "conditional request." Because of its conditional nature, the "request," at the moment IBM received it, was not in fact requesting anything-rather it merely expressed an interest in receiving the relevant documents should certain events occur. In other words, Dr. Stallings did not show a clear intent to receive plan documents. Cf. Haberern, 24 F.3d at 1505-06. Moreover, it is not clear to the Court that Dr. Stallings herself viewed the April 2005 letter as a statutory request since she did not request the documents again until over one year later in October 2006, she did not follow up with the Employee Services Center to get the requested documents per the October 2005 denial letter, and she did not file suit to remedy the violation for over three years. Simply put, the

equivocal nature of the "request" is insufficient to support a violation of a penal statute that is narrowly construed and interpreted. *See Groves*, 803 F.2d at 118. Thus, the Court finds no violation of § 502(c).

#### 2. Discretionary penalty

\*13 Even if the Court had found a violation of § 502(c), a statutory penalty would not otherwise have been warranted under the circumstances. Penalties under § 502(c)(1) are in the discretion of the court. *Maiuro*, 843 F.Supp. at 943. This discretion permits the court to levy no sanction even where a technical violation is found. *See Gillis v. Hoechst Celanese Corp.*, 4 F.3d 1137, 1148 (3d Cir.1993). In levying a penalty, the court may look for "'bad faith or intentional conduct on the part of the administrator, the length of the delay, the number of requests made and documents withheld, and the existence of any prejudice to the participant or beneficiary.' " *Boyadjian v. Cigna Companies*, 973 F.Supp. 500, 505 (D.N.J.1997) (quoting *Pagovich v. Moskowitz*, 865 F.Supp. 130, 137 (S.D.N.Y.1994)). Prejudice to the participant or beneficiary is not required. *Maiuro*, 843 F.Supp. at 943.

Many factors weigh against finding a penalty in this dispute. First, nothing suggests that IBM's failure to respond to the April 2005 "request" was in bad faith or intentional, but rather the delay was seemingly caused by the unusual circumstances of the "request" (e.g., it was conditional upon the results of a benefits adjudication that took six months to complete). Second, while the delay between the purported request and the actual disclosure was over one year, the delay is again readily explained by the unusual circumstances of the "request." Third, Dr. Stallings made only one additional request after April 2005 and that request was quickly fulfilled. Moreover, Dr. Stallings-though not required to by ERISA-did not follow up on IBM's October 2005 letter explaining how to get plan documents, thus indicating that she had not really requested them. Fourth, while Plaintiffs repeatedly claim prejudice as a result of the delay, see, e.g., Plaintiffs' br. at 22, Dr. Stallings appears to in fact have had the plan documents as early as June 12, 2003, which destroys any claim of prejudice. See Plaintiffs' undisputed facts at ¶ 21. Plaintiffs' counter to this assertion is a half-hearted acknowledgment that while Dr. Stallings received the letter stating the requested documents were enclosed, she only received the documents "at some point after March 31, 2003." Id. Plaintiffs readily have in their possession and control whether or not Dr. Stallings received the requested documents in 2003 and yet fail to so disclose. Therefore, on the totality of the circumstances, a

penalty would not otherwise have been warranted under the circumstances.

However, because the Court held above that Dr. Stallings did not in fact make a statutory request, Plaintiffs' motion for summary judgment as to Count Three is denied, and IBM's motion for summary judgment as to Count Three is granted.

#### D. Count Four: State Law Claims

In Count Four, Plaintiffs bring state law claims for unjust enrichment, breach of implied contract and covenant of good faith and fair dealing against IBM. IBM argues that these claims are pre-empted by ERISA. IBM SJ br. at 19-21. This argument is unopposed by the Plaintiffs. Because the claim relates to an ERISA plan, Count Four is pre-empted and IBM is granted summary judgment.

\*14 Under § 514(a) of ERISA, 29 U.S.C. § 1144(a), all state laws that "relate to" an employee benefit plan covered by the Act are pre-empted. The purpose of the pre-emption clause is to ensure uniform regulation and administration of employee benefit plans. New York State Conference of Blue Cross & Blue Shield Plans v. Travelers Ins. Co., 514 U.S. 645, 657, 115 S.Ct. 1671, 131 L.Ed.2d 695 (1995). The Supreme Court has held that the "relate to" language is deliberately broad in scope and Congress intended that it be "expansively applied." Ingersoll-Rand Co. v. McClendon, 498 U.S. 133, 138-39, 111 S.Ct. 478, 112 L.Ed.2d 474 (1990). State law includes "all laws, decisions, rules, regulations, or other State action having the effect of law [.]" § 1144(c)(1). Notwithstanding the broad pre-emption language, the pre-emption clause does not apply where a state law " 'has only a tenuous, remote, or peripheral connection with covered plans, as is the case with laws of general applicability." Travelers, 514 U.S. at 661 (quoting District of Columbia v. Greater Washington Bd. of Trade, 506 U.S. 125, 130 n. 1, 113 S.Ct. 580, 121 L.Ed.2d 513 (1992)).

The established test for whether a state law "relates to" a covered plan is whether the law "has a connection with or reference to such a plan." *Ingersoll-Rand*, 498 U.S. at 139 (quotations removed). In part, the test means that a state law is pre-empted if the cause of action is premised on the existence of a plan. *See id.* at 140 (holding state law claim for wrongful termination pre-empted where claim depended on showing that employee was terminated to avoid payment of pension benefits).

Plaintiffs' claim in Count Four relates to a severance benefits package. Certain severance benefits plans are covered by ERISA where the employer "has expressed an intention to provide benefits on a regular and long-term basis.'" *Brennan v. Cephalon, Inc.*, No. 04-cv-3241, 2005 WL 2807195, at \*15 (D.N.J. Oct.25, 2005) (quoting *Gruber v. Hubbard Bert Karle Weber, Inc.*, 159 F.3d 780, 789 (3d Cir.1998)), *aff'd*, 298 Fed. Appx. 147 (3d Cir.1998). IBM proffers that the severance package was an ERISA plan and attaches the terms of the plan as an exhibit to its motion for summary judgment. *See* IBM SJ br. at 21, Ex. G. The text of the plan itself states that it is subject to ERISA. *Id.* at Ex. G at IBM00388. Plaintiffs offer no response to this assertion.

Based upon a review of the plan and the supporting argument from IBM, the Court finds that IBM's motion for summary judgment properly supports that the severance plan is an ERISA plan. See Fed.R.Civ.P. 56(e)(2). Because Plaintiffs have failed to offer specific facts showing that a genuine issue exists as to whether or not the severance plan is an ERISA plan, see id., and because Plaintiffs' state law claims are dependent upon the existence of the plan, the Court finds that Plaintiffs' state law claims are pre-empted. Therefore, IBM is granted summary judgment as to Count Four.

#### E. Rule 56(f) Defense

\*15 Plaintiffs oppose summary judgment under Fed.R.Civ.P. 56(f) because discovery is incomplete. Under Rule 56(f), a party opposing a motion for summary judgment may show by affidavit that "it cannot present facts essential to justify its opposition," and upon such affidavit, the court may deny the motion or order a continuance. A Rule 56(f) affidavit must specify "what particular information is sought; how, if uncovered, it would preclude summary judgment; and why it has not been previously obtained." *Dowling v. City of Philadelphia*, 855 F.2d 136, 139-40 (3d Cir.1988).

Plaintiffs proffer that further discovery is necessary into the "degree of discretion afforded to Plan fiduciaries" and into "internal safeguards intended to check over-zealous adjudication practices." Plaintiffs' br. at 22-23. Plaintiffs' discovery relates to their claims in Count One seeking LTD benefits because of the standard of review used in evaluating Dr. Stallings' claim for benefits. However, because the Court finds that Plaintiffs' Count One claim is untimely and does not reach the standard of review issue, Plaintiffs' desired discovery has no bearing on the motions before the Court. Thus, Plaintiffs' Rule 56(f) defense is denied.

#### F. Motion to Amend

Plaintiffs filed a motion to amend under Federal Rule of Civil Procedure 15(a) with their cross motion for partial summary judgment on April 1, 2009. Docket No. 22. Plaintiffs seek to add three state law claims against IBM and John Doe(s) based on the denial of benefits under the Sickness and Accident Plan and one state law claim based on intentional infliction of emotional distress. Plaintiffs' br. at Ex. RR. Defendant IBM opposes the motion arguing that Plaintiffs have failed to show the new claims have "substantial merit" or that they are supported by "substantial and convincing evidence," and on the basis that allowing the amendments will cause undue delay and prejudice. IBM reply br. at 3-7. The Scheduling Order for this case set the deadline for amending pleadings as December 31, 2008, Docket No. 13 at ¶ 5, and that deadline was not changed by Magistrate Judge Schneider's subsequent amended Order on May 8, 2009. Docket No. 34.

A plaintiff may amend its complaint after a responsive pleading has been filed only with the opposing party's written consent or with leave of court. Fed.R.Civ.P. 15(a)(2). "The court shall freely give leave when justice so requires." Id. " '[P]rejudice to the non-moving party is the touchstone for denial of an amendment." "Lorenz v. CSX Corp., 1 F.3d 1406, 1413-14 (3d Cir.1993) (quoting Cornell & Co. v. Occupational Safety & Health Review Comm'n, 573 F.2d 820, 823 (3d Cir.1978)). "In the absence of substantial or undue prejudice, denial instead must be based on bad faith or dilatory motives, truly undue or unexplained delay, repeated failures to cure the deficiency by amendments previously allowed, or futility of amendment." Id. at 1414. Leave to amend may be appropriate even if "considerable proceedings [have] transpired" or discovery is complete. See Coventry v. United States Steel Corp., 856 F.2d 514, 518, 519 (3d Cir.1988).

\*16 Notwithstanding the liberal amendment standards in Rule 15, leave to amend is also governed by Federal Rule of Civil Procedure 16 in certain circumstances. Rule 16 governs pretrial management and specifically scheduling orders. Under Rule 16(b)(4), a scheduling order may only be modified for "good cause." Where deadlines for amending pleadings are the subject of a scheduling order and the deadlines have passed, the moving party must meet Rule 16's good cause standard in order to amend. See Eastern Minerals & Chemicals Co. v. Mahan, 225 F.3d 330, 340 (3d Cir.2000) (affirming district court's denial of motion to amend on basis of Rule 16(b) where amendment sought six months after deadline); Dimensional Commc'ns, Inc. v. Oz Optics,

LTD., 148 Fed. Appx. 82, 85 (3d Cir.2005) (affirming denial where leave to amend sought five months after deadline, noting Third Circuit has adopted a "good cause" standard for amending); see also Assadourian v. Harb, No. 06-cv-896, 2008 WL 4056361, at \*2 (D.N.J. Aug.28, 2008) (holding motion to amend after scheduling order deadline has passed is treated as motion to amend pretrial scheduling order). Rule 16 governs in these situations rather than Rule 15 because scheduling orders would otherwise "be nullified if a party could inject amended pleadings upon a showing of less than good cause after scheduling deadlines have expired." Harrison Beverage Co. v. Dribeck Importers, Inc., 133 F.R.D. 463, 469 (D.N.J.1990).

Plaintiffs purported "good cause" for amending the Complaint after the scheduling deadline has passed is that they only became aware of the ability to raise the proposed claims upon review of 1900+ documents supplied by IBM during discovery. Plaintiffs' reply br. at 4-5, 9-10. Plaintiffs claim that only upon review of these documents, and upon review of Dr. Stallings' personal records, did they realize that they had additional grounds for relief under state law. *Id.* at 9-10. Plaintiffs undisputedly received IBM's documents in October 2008 as part of IBM's initial disclosures under Rule 26, *id.* at 3, and presumably had Dr. Stallings' records throughout.

The Court finds that Plaintiffs have not stated good cause for allowing an amendment after the December 31, 2008 Scheduling Order deadline. Even if IBM's records were "unindexed" and "out of sequence" as Plaintiffs assert, i Plaintiffs' reply br. at 3, Plaintiffs still had over 60 days in which to review the records and state additional claims. Even if such a task could not be completed in that time, Plaintiffs could have moved for an extension of the pleadings deadline, which was not done and not explained. *Cf. Assadourian*, 2008 WL 4056361, at \*3 (holding party lacked good cause for amendment where failed to explain why he did not request an extension to file an amended pleading).

Moreover, Plaintiffs had sufficient information to state the proposed claims well in advance of the Scheduling Order deadline. Perhaps the most common basis for finding a lack of good cause is the party's knowledge of the potential claim before the deadline to amend. *See Dimensional Commc'ns*, 148 Fed. Appx. at 85 ("Magistrate Judge Arleo found that Oz could not satisfy Rule 16(b)'s good cause requirement because Oz was in possession of the facts underlying the proposed counterclaim well before the

amendment deadline."); Assadourian, 2008 WL 4056361, at \*3 ("Plaintiff concedes that, 'prior to the Harb deposition [,] he was in possession of random and isolated documentary materials which seemed to support the proposed RICO claim amendments."); Prime Ins. Syndicate v. United Risk Mgmt. Srvcs., No. 03-cv-1050, 2006 WL 2085388, at \*5 (D.N.J. July 25, 2006) ("Plaintiff provided no reason for why it could not have asserted these new claims against Krauze within the requisite deadlines. In fact, in Plaintiff's brief for this appeal, it acknowledges that it 'had knowledge of the OTSC allegations since October 2004.' "); Harrison Beverage, 133 F.R.D. at 469 ("This is most definitely not a motion in which any of defendant's six proposed new affirmative defenses arose from recent discovery in the case."). Plaintiffs here undisputedly had all of the relevant documents necessary to state the proposed state law claims before the amendment deadline had run. In fact, a reading of Plaintiffs' Complaint without the claims for relief would lead an ordinary reader to believe Plaintiffs were about to seek relief for denial of both S & A benefits and LTD benefits. However, Plaintiffs for some reason did not state an S & A claim in the original Complaint, but instead have only attempted to do so-tellinglyafter IBM and Metlife tipped their hand with dispositive motions that dispatched Plaintiffs' existing claims. For these reasons, Plaintiffs have failed to show good cause why they should be allowed to amend the Complaint after the Scheduling Order deadline, and Plaintiffs' motion to amend is denied.

\*17 Notwithstanding, even if Plaintiffs could show good cause, the amendment would still be disallowed under Rule 15 because of the prejudice to IBM. Prejudice may result from an amendment where a party has to change "tactics or case theories" because of the new claims. See Kiser v. Gen. Elec. Corp., 831 F.2d 423, 428 (3d Cir.1987) (holding no prejudice where non-moving party could not show amendment would affect tactics or case theories). Prejudice may also result where the amendment will require the reopening of discovery, would delay resolution of the matter, or would unnecessarily increase the cost of litigation. See Textron Fin'l-New Jersey, Inc. v. Herring Land Group, LLC, No. 06-cv-2585, 2009 WL 690933, at \*5 (D.N.J. Mar.11, 2009).

IBM asserts that if an amendment is allowed now, it will be prejudiced because it navigated discovery solely on the basis of Plaintiffs' existing claims for LTD benefits, and because the new claims will deprive IBM of the opportunity to develop defenses to the new claims. IBM reply br. at 6-7. The Court

is persuaded by these claims. Allowing Plaintiffs to amend now will most assuredly require re-opening of discovery. Plaintiffs' claims admittedly arise only under state law, and until now, discovery has proceeded as if federal law governs. Moreover, Plaintiffs have known since 2002 that Dr. Stallings did not receive S & A benefits and have believed for some time that she was wrongly denied relief. See IBM SJ br. at Ex. L (April 1, 2005 letter from Richard Yaskin to IBM). To permit Plaintiffs to amend the Complaint now to state claims for relief that have existed for some time would unnecessarily delay this litigation and increase costs. Cf. Lorenz, 1 F.3d at 1414 (affirming denial of leave to amend where plaintiff had necessary information to state claim when filed original complaint). Thus, even if Plaintiffs could show good cause under Rule 16, their motion to amend would be denied under Rule 15.

Therefore, Plaintiffs' motion to amend is denied.

#### G. John Doe Defendants

Plaintiffs have stated claims against John Doe defendants. Under Federal Rule of Civil Procedure 21, "the court may at any time, on just terms, add or drop a party." A court my drop John Doe defendants under this rule. *Adams v. City of Camden*, 461 F.Supp.2d 263, 271 (D.N.J.2006). Because Plaintiffs have failed to identify any unknown defendants, and because Plaintiffs' claims otherwise fail for the reasons discussed above, the Court dismisses the John Doe defendants.

#### **IV. Conclusion**

For the foregoing reasons, the motion for summary judgment filed by IBM and R.A. Barnes is **GRANTED.** The motion to dismiss filed by Metropolitan Life Insurance Company is **GRANTED.** The motion for partial summary judgment filed by Plaintiffs Mary and Patricia Stallings is **DENIED.** The motion to amend filed by Plaintiffs Mary and Patricia Stallings is **DENIED.** The John Doe defendants are **DISMISSED.** 

#### All Citations

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# **Tab 30**

2011 WL 2115819 Only the Westlaw citation is currently available. United States District Court, D. New Jersey.

TAKEDA PHARMACEUTICAL CO., LIMITED, et al., Plaintiff,

ZYDUS PHARMACEUTICALS USA INC., et al., Defendant.

v.

Civil Action No. 10–1723 (JAP). | May 25, 2011.

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#### **OPINION**

PISANO, District Judge.

\*1 Plaintiffs Takeda Pharmaceutical Company Limited, Takeda Pharmaceuticals North America, Inc., Takeda Pharmaceuticals LLC, Takeda Pharmaceuticals America, Inc., (collectively, "Takeda") and Ethypharm, S.A. ("Ethypharm," together with Takeda, "Plaintiffs") bring this patent infringement action under the Hatch-Waxman Act against defendants Zydus Pharmaceuticals (USA) Inc. and Cadila Healthcare Limited (together, "Defendants") claiming infringement of three patents alleged to cover Takeda's Prevacid SoluTab product ("SoluTab"). These patents are U.S. Patent Nos. 6,328,994 (the "'994 patent"), 7,431,942 the "'942 patent"), and 5,464,632 (the "'632 patent"). Presently before the Court is a motion by Plaintiffs to dismiss Defendants' Seventh Counterclaim pursuant to Federal Rule of Civil Procedure 12(b)(6) and to strike certain allegations in the counterclaims of patent misuse pursuant to Rule 12(f). The

Court considers the matter without oral argument pursuant to Rule 78. For the reasons below, Plaintiffs' motion is granted.

#### A. Defendants' Counterclaims

Defendants Second Amended Answer and Counterclaims contain seven counterclaims. The Seventh Counterclaim, challenged in its entirety by Plaintiffs, alleges that the '632 patent is unenforceable due to patent misuse. Two types of misuse are alleged. First, Defendants allege that Takeda, "at the urging of" Ethypharm, "intentionally mislisted [the '632 patent] in the Orange Book<sup>1</sup> with respect to" SoluTab. Counterclaim ¶ 43. Defendants assert that Plaintiffs listed the '632 patent in the Orange Book even though "they were well aware that [the'632 patent] does not cover in any of its claims the actual composition of the product [SoluTab]. Id. ¶ 45. See also id. ¶ 47 ("At the time of the listing, and at the time of the commencement of this suit, [Plaintiffs] were aware that none of the claims of [the '632 patent] covered the actual composition of [SoluTab]."). Defendants' assert that as a result of the alleged mislisting, under the Hatch-Waxman statutory scheme Plaintiffs were able to obtain a 30-month stay from the FDA's final approval of Defendants' ANDA by filing a timely infringement suit.

When the FDA approves a new drug application, it publishes a listing of the drug and related patents in *Approved Drug Products with Therapeutic Equivalence Evaluations*, also known as the "Orange Book."

Second, Defendants allege that Plaintiffs, being aware that the '632 patent did not cover SoluTab, falsely marked SoluTab's packaging with the '632 patent. It is asserted that Plaintiffs "purposely undertook deceitful marking of the patent number on its labeling affixed to each and every bulk product package," and understood that by doing so "they were deceitfully indicating to the public that the product contained therein was protected by such patent." *Id.* ¶ 51. Defendants also bring a *qui tam* action pursuant to 35 U.S.C. § 292.

Three other counterclaims contain allegations of patent misuse. In the Fourth, Fifth and Sixth Counterclaims, which seek declarations of invalidity as to the '994 patent, the '942 patent and the '632 patent, respectively, Defendants allege that the claims in each of the patents are "invalid for failure to satisfy the provisions of the patent laws of the United States." *Id.* ¶¶ 31, 35, 39. Immediately thereafter, Defendants further allege that "the filing of an objectively baseless lawsuit based on a patent that is understood to be invalid for obviousness

and continuing the prosecution of such case ... constitutes patent misuse ...". *Id.* ¶¶ 32, 36, 40.

\*2 Plaintiffs move to dismiss the Seventh Counterclaim and to strike the patent misuse allegations of the invalidity counterclaims (specifically paragraphs 32, 36 and 40). First, they allege that the Hatch-Waxman Act does not permit Defendants' patent misuse counterclaim based on mislisting. Second, they contend that Defendants do not adequately plead mislisting or false marking under the heightened pleading standard of Federal Rule of Civil Procedure 9(b) or under Rule 8's notice pleading requirements. As to the Seventh Counterclaim, Plaintiffs allege that Defendants do not set forth any supportive facts as to: (a) how SoluTab falls outside the scope of the '632 Patent; (b) Plaintiffs' knowledge of the same; (c) Plaintiffs' deceptive intent with respect to either the purported mislisting or the false marking; and (d) how Ethypharm played any role in the purported mislisting or false marking of Takeda's SoluTab. Similarly, with respect to the allegations of patent misuse within the invalidity counterclaims, Plaintiffs contend that Defendants do not set forth any supportive facts as to (a) the specific prior art rendering each of the three patents-in-suit obvious; (b) Plaintiffs' knowledge of the same; and (c) the "objectively baseless" nature of this lawsuit as to each of the three patentsin-suit.

#### B. Legal Standard

Under Federal Rule of Civil Procedure 12(b)(6), a court may grant a motion to dismiss if the complaint fails to state a claim upon which relief can be granted. The Supreme Court set forth the standard for addressing a motion to dismiss under Rule 12(b)(6) in Bell Atl. Corp. v. Twombly, 550 U.S. 544, 562, 127 S.Ct. 1955, 167 L.Ed.2d 929 (2007). The Twombly Court stated that, "[w]hile a complaint attacked by a Rule 12(b)(6) motion to dismiss does not need detailed factual allegations, ... a plaintiff's obligation to provide the grounds of his entitle[ment] to relief requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do[.]" Id. at 555 (internal citations omitted); see also Baraka v. McGreevey, 481 F.3d 187, 195 (3d Cir.2007) (stating that standard of review for motion to dismiss does not require courts to accept as true "unsupported conclusions and unwarranted inferences" or "legal conclusion[s] couched as factual allegation[s]." (internal quotation marks omitted)). Therefore, for a complaint to withstand a motion to dismiss under Rule 12(b)(6), the "[f]actual allegations must be enough to raise a right to relief above the speculative level, ... on the assumption that all the allegations in the complaint are true (even if doubtful in fact) ..." *Twombly*, 550 U.S. at 555 (internal citations and footnote omitted).

The Supreme Court has emphasized that, when assessing the sufficiency of a civil complaint, a court must distinguish factual contentions and "[t]hreadbare recitals of the elements of a cause of action, supported by mere conclusory statements." *Ashcroft v. Iqbal*, — U.S. —, —, 129 S.Ct. 1937, 1949, 173 L.Ed.2d 868 (2009). When evaluating a motion to dismiss for failure to state a claim, district courts conduct a two-part analysis.

\*3 First, the factual and legal elements of a claim should be separated. The District Court must accept all of the complaint's well-pleaded facts as true, but may disregard any legal conclusions. Second, a District Court must then determine whether the facts alleged in the complaint are sufficient to show that the plaintiff has a "plausible claim for relief." In other words, a complaint must do more than allege the plaintiff's entitlement to relief. A complaint has to "show" such an entitlement with its facts.

Fowler v. UPMC Shadyside, 578 F.3d 203, 210–11 (3d Cir.2009) (quoting Iqbal, 129 S.Ct. at 1949–50). A complaint will be dismissed unless it "contain[s] sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.' " *Id.* at 1949 (quoting *Twombly*, 550 U.S. at 570). This "plausibility" determination will be "a context-specific task that requires the reviewing court to draw on its judicial experience and common sense." Fowler, 578 F.3d at 211 (citations omitted).

#### C. Analysis

#### 1. Whether Defendants' Misuse Claim is Precluded

The Court first addresses Plaintiffs' argument that the Hatch—Waxman Act does not permit Defendants to assert a patent misuse counterclaim based on the allegedly improper listing of the '632 patent in the Orange Book. Patent misuse is one of the equitable defense to patent infringement. See U.S. Philips Corp. v. International Trade Com'n, 424 F.3d 1179, 1184 (Fed.Cir.2005). "The patent misuse doctrine, born from the equitable doctrine of unclean hands, is a method of limiting abuse of patent rights separate from the antitrust laws. B. Braun Medical, Inc. v. Abbott Laboratories, 124 F.3d 1419, 1426 (Fed.Cir.1997). "The key inquiry under this fact-intensive doctrine is whether, by imposing the condition, the patentee has impermissibly broadened the physical or

temporal scope of the patent grant with anticompetitive effect." *Id.* (quotations omitted).

In support of their argument, Plaintiffs first point to the authorization provided the Act for a defendant in an infringement suit to assert a counterclaim seeking an order requiring an NDA holder to correct or delete patent information it submitted for listing in the Orange Book. *See* 21 U.S.C. § 355(j)(5)(C)(ii). Title 21, Section 355(j)(5)(C)(ii) of the United States Code provides as follows:

#### (ii) Counterclaim to infringement action

#### (I) In general

If an owner of the patent or the holder of the approved application under subsection (b) of this section for the drug that is claimed by the patent or a use of which is claimed by the patent brings a patent infringement action against the applicant, the applicant may assert a counterclaim seeking an order requiring the holder to correct or delete the patent information submitted by the holder under subsection (b) or (c) of this section on the ground that the patent does not claim either—

- \*4 (aa) the drug for which the application was approved; or
- (bb) an approved method of using the drug.

#### (II) No independent cause of action

Subclause (I) does not authorize the assertion of a claim described in subclause (I) in any civil action or proceeding other than a counterclaim described in subclause (I).

21 U.S.C. § 355(j)(5)(C)(ii). Plaintiffs argue that this provision limits counterclaims based upon mislisting to those specified in the statute.

Plaintiffs also rely upon *Schwarz Pharma*, *Inc. v. Teva Pharmaceuticals USA*, *Inc.*, 2005 WL 4158850 (D.N.J.2005). In the context of a Hatch–Waxman infringement action, the court in *Schwarz Pharma* denied a motion to amend that sought to add a counterclaim for patent misuse based on facts alleging the improper listing of a patent in the Orange Book. Relying on primarily on *Mylan Pharmaceuticals*, *Inc. v. Thompson*, 268 F.3d 1323 (Fed.Cir.2001) ("*Mylan*"), the court in *Schwarz Pharma* held that "improper listing in the Orange Book cannot be the basis of a misuse defense." 2005 WL 4158850 at \*7.

Mylan involved a claim that a particular patent was improperly listed in the Orange Book because the patent did not claim a drug for which an NDA had been submitted, as is required by 21 U.S.C. § 355(b)(1) ("The applicant shall file with the application the patent number and the expiration date of any patent which claims the drug for which the applicant submitted the application or which claims a method of using such drug and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug."). In Mylan, an ANDA applicant filed a declaratory judgment action against the NDA holder and the FDA alleging that the patent at issue had been improperly listed in the Orange Book because the patent did not cover the branded drug product or a method for using it. The plaintiff sought declaratory and injunctive relief including an injunction against the NDA holder requiring it to delist the patent from the Orange Book and an injunction against the FDA to immediately approve the plaintiff's ANDA. The district court granted the relief sought but, on appeal from the NDA holder the Federal Circuit reversed, finding that the Federal Food, Drug, and Cosmetic Act ("FFDCA"), 21 U.S.C. §§ 301, et seq., did not provide a private right of action for "delisting" a patent from the Orange Book. The Federal Circuit rejected the ANDA applicant's argument that its action arose under the patent laws (Title 35 of the United States Code):

Mylan[, the ANDA applicant,] argues that the action Bristol, the declaratory judgment defendant, would have brought is an action for patent infringement under 35 U.S.C. § 271(e)(2). This section provides that an applicant infringes a patent if it submits an ANDA "for a drug claimed in a patent or the use of which is claimed in a patent ... before the expiration of such patent." 35 U.S.C. § 271(e)(2) (1994). Mylan argues that had it filed an ANDA with a Paragraph IV certification, it would have been charged with infringing the '365 patent. One of the defenses, which Mylan argues would be available to it in Bristol's hypothetical patent infringement suit, is that Mylan should not have been required to file a Paragraph IV certification in the first instance because the '365 patent did not claim BuSpar or an approved method of using BuSpar, and accordingly, Bristol improperly submitted the '365 patent for listing in the Orange Book.

In a declaratory judgment action, to determine which federal law is the basis of the declaratory plaintiff's cause

of action, the court looks to the action that the declaratory defendant would have brought. *Mylan*, 268 F.3d at 1330.

\*5 This assertion, however, is not a recognized defense to patent infringement.

268 F.3d at 1330–31 (footnote added).

Having rejected the ANDA applicant's argument that its claim arose under the patent laws, the court then determined that the Hatch—Waxman Amendments to the FFDCA also provided no avenue for the relief sought. Ultimately, the court concluded that the ANDA applicant was improperly attempting to bring an action for delisting under the FFDCA. See 268 F.3d at 1332 ("[W]e are forced to conclude that Mylan's action here ... is in essence an attempt to assert a private right of action for 'delisting' under the FFDCA.")

As noted in *Schwarz Pharma*, "[i]n response to *Mylan*, Congress created a limited cause of action under FFDCA allowing a party accused of infringement under 35 U.S.C. § 271(e)(2) to bring a counterclaim to delist an allegedly improperly listed patent. 21 U.S.C. § 355(c)(3)(D)(ii)(I)." 2005 WL 4158850, \*7 n. 1. As noted above, this provision permits a counterclaim seeking an order requiring an NDA holder to correct or delete an Orange Book listing.

Not all courts are in agreement with Schwarz Pharma on the question of whether mislisting can form the basis of a misuse counterclaim. See Eli Lilly and Co. v. Wockhardt Ltd., 2010 WL 2605855 (S.D.Ind. June 22, 2010) (noting disagreement among courts; finding not futile amendments to add defense and counterclaim of patent misuse based upon improper listing); Novo Nordisk A/S v. Caraco Pharmaceutical Laboratories, Ltd., 649 F.Supp.2d 661 (E.D.Mich.2009) (rejecting Schwarz Pharma; denying motion to strike misuse defense based upon allegations of improper listing); Astra Aktiebolag v. Kremers Urban Development Co., 61 U.S.P.Q.2d 1767 (S.D.N.Y.2001) (denying motion to dismiss counterclaim alleging misuse where it was alleged the patent owner falsely certified that listed patent covered the approved product and that such false certification forced defendant to file a Paragraph IV certification). As this Court views the issue, based upon its reading of Mylan, the question boils down to whether Defendant's counterclaim is substantively analogous to a private action for violation of the FFDCA, as the FFDCA does not create a private cause of action, but rather confers all enforcement authority to the United States. 21 U.S.C. § 337(a); In re Orthopedic Bone Screw Prod. Liab. Litig., 193 F.3d 781, 788 (3d Cir.1999) ("It is well settled ... that the [F]FDCA creates no private right of action."). As Mylan held, this rule extends to actions based solely on a party's violation of a requirement imposed by the FFDCA. Mylan, 268 F.3d at 1332; see also Mylan Lab., Inc. v.. Matkari, 7 F.3d 1130, 1139 (4th Cir.1993) (holding that claim brought under Lanham Act based solely on alleged violation of FFDCA violates principle that FFDCA does not create private cause of action). However, as noted in Mylan, the standards enunciated by the FFDCA may be used to support an independent cause of action. 268 F.3d at 1332. Accord in re Orthopedic Bone Screw Prod. Liab. Litig., 193 F.3d at 790 ("A claim of civil conspiracy cannot rest solely upon the violation of a federal statute for which there is no corresponding private right of action."); Zenith Lab., Inc. v. Abbott Lab., 1996 WL 33344963, \*5 (D.N.J. Aug.7, 1996) ("[A] violation of the FFDCA that gives rise to a separate cause of action does not necessarily lead to the conclusion that such a claim is preempted.").

\*6 By way of its patent misuse counterclaim, Defendants are alleging that the '632 patent should be deemed unenforceable because Plaintiffs have invoked the provisions of the Hatch—Waxman Act to "impermissibly broaden[] the physical or temporal scope of the patent grant with anticompetitive effect." B. Braun Medical, Inc.., 124 F.3d at 1426. As such, reference to the standards enunciated by FFDCA is required to support the claim that Plaintiffs have improperly broadened the scope of their patent. However, like in Mylan, Defendants' misuse counterclaim here does not merely use those standards to support an independent claim. The central, if not sole, element of Defendants' misuse claim is "that [Plaintiffs] improperly listed the ['632] patent because it does not comply with the requirements" of the FFDCA. Mylan, 268 F.3d at 1332. Indeed, the counterclaim alleges that

an [NDA] applicant is permitted ONLY to "submit information ... on those patents that claim the drug substance that is the subject of the pending or approved application or that claim a drug substance that is the same as the active ingredient that is the subject of the approved or pending application." ... Counterclaim Defendants listed [the '632 patent], containing solely composition claims, in the Orange Book although they were well aware that [the '632 patent] does not cover in any of its claims the actual composition of [SoluTab]. Such mislisting constitutes patent misuse.

Counterclaim ¶¶ 44–45 (citation omitted). As such, the Court agrees with Plaintiffs' argument that Defendants' patent misuse counterclaim is precluded here. At its core, Defendants' counterclaim alleges no more than that Plaintiffs violated the FFDCA. Therefore, such a claim is

prohibited. Consequently, Defendants' misuse claim based upon allegations that Plaintiffs listed the '632 patent despite the patent not meeting the statutory requirements for listing is dismissed.

### 2. Whether Seventh Counterclaim Meets Applicable Pleading Standards

Even if the Court had found that Defendants' mislisting counterclaim was not precluded, that claim as well as the false marking claim, nevertheless fails. Plaintiffs contend that the allegations for mislisting and false marking in the Seventh Counterclaim fail to meet the notice pleading standards of Rule 8 and/or the heightened pleading requirements of Rule 9(b) because, according to Plaintiffs, the Seventh Counterclaim (1) does "not identify any elements of any claim of the '632 patent that Takeda's SoluTab fails to meet," Pl. Brf. at 6; and (2) does not set forth any facts with respect to deceptive intent on the part of Plaintiffs. As to the first assertion, the Court notes that a central allegation of the counterclaim is that "none of the claims of [the '632 patent] covers the actual composition of Prevacid SoluTab." Counterclaim ¶ 47. However, the counterclaim contains no facts upon which this allegation is based. While a claim need not contain detailed factual allegations, it must contain some facts from which it can be inferred that such an allegation is plausible. "Conclusory allegations ... are not entitled to an assumption of truth at any stage in litigation." In re BP Lubricants USA Inc., 637 F.3d 1307, 1312 (Fed.Cir.2011)

\*7 As to Defendants' false marking claim, case law is clear that Defendants must plead facts showing an intent to deceive and, further, that pleading a claim for false marking falls within the scope of Rule 9(b). Juniper Networks, Inc. v. Shipley, — F.3d —, 2011 WL 1601995, \*3 (Fed.Cir.2011) ( "A false marking claim requires an intent to deceive the public and sounds in fraud. As such, false marking claims must satisfy the heightened pleading standard of Fed.R.Civ.P. 9(b), which provides that "a party must state with particularity the circumstances constituting fraud or mistake.") (citations omitted). To satisfy Rule 9(b), although knowledge and intent may be averred generally and a plaintiff may plead upon information and belief, the complaint must contain sufficient underlying facts from which a court may reasonably infer that the defendant acted with the requisite state of mind. In re BP Lubricants USA Inc., 637 F.3d at 1311. Based on the underlying factual allegations of the counterclaim in this case, in order to allege the requisite intent to deceive in the § 292 context, Defendants' claim should provide "some objective indication to reasonably infer that the defendant was aware that the patent" did not cover the SoluTab product to which the patent was affixed. *Id*. (citing *Clontech Labs., Inc. v. Invitrogen Corp.*, 406 F.3d 1347, 1352 (Fed.Cir.2005) (proof that the party making a misrepresentation had knowledge of its falsity "is enough to warrant drawing the inference that there was fraudulent intent").

In response to Plaintiffs' motion, Defendants point to three allegations they claim are sufficient to plead the element of deceitful intent:

(1) the false marking occurred "by marking the patent number on its labeling affixed to each and every bulk package." (Counterclaims ¶ 50); (2) a sophisticated drug manufacturer such as Takeda would understand that the marking of such patent number would "dissuade generic manufacturers from seeking to file an ANDA on the product and would be understood by the "public, including generic manufacturers, pharmacies, and drug retailers, that until the expiration of such patent that a generic product could not be made, used, sold, offered for sale or imported into the United States without risking patent infringement damages." (Counterclaims ¶ 51 and 52); and Takeda, as a sophisticated drug manufacturer, would understand that applying the mark to its bulk product package "would delay entrance into supply agreements by pharmacies and other drug retailers with generic manufacturers based on a perceived fear of potential patent infringement damages in accepting an offertosell" and "would dissuade pharmacies, drug retailers, health professionals and consumers from seeking generic equivalents to the product." (Counterclaims ¶¶ 53 and 54). Def. Brf. at 11-12. Such allegations, however, fall short of satisfying the relevant pleading standard with respect to element of intent, as they state little more than that Plaintiff marked the patent number on its product and then describe the consequences that allegedly flow from a patent being marked on a drug product. No facts are pled from which the Court can infer that Plaintiffs falsely marked the product with an intent deceive the public. As noted above, the pleading does not allege facts, for example, from which it can be inferred that Plaintiff knew that the patent did not cover the product. Consequently, for the reasons above, the Seventh Counterclaim shall be dismissed.

3. Whether Defendants' Allegation of Patent Misuse In the Fourth, Fifth and Six Counterclaims Meet the Should be Stricken

\*8 The Fourth, Fifth and Sixth Counterclaims, which seek a declaration of patent invalidity for the '994, '942 and '632 patent respectively, each contain the following identical paragraph:

[T]he filing of an objectively baseless lawsuit based on a patent that is understood to be invalid for obviousness and the continuing prosecution of such case after the rendering of the U.S. Supreme Court case of *KSR International Co. v. Teleflex.*, 127 S.C. 1727 (2007), constitutes patent misuse, and litigation misconduct.

Counterclaims ¶¶ 32, 36, and 40. Plaintiffs argue that these paragraphs should be stricken pursuant to Rule 12(f) because these assertions are unsupported by any factual allegations. Rule 12(f) of the Federal Rules of Civil Procedure provides: "The court may strike from a pleading an insufficient defense or any redundant, immaterial, impertinent, or scandalous matter." Fed.R.Civ.P. 12(f). "Immaterial" material is that "which has no essential or important relationship to the claim for relief or the defenses being pleaded." Delaware Health Care, Inc. v. MCD Holding Co., 893 F.Supp. 1279, 1291-1292 (D.Del.1995). "Impertinent" material does not pertain, and is not necessary, to the issues in question. *Id.* at 1292. "Scandalous" material "improperly casts a derogatory light on someone ... reflect cruelly upon the defendant's moral character, use[s] repulsive language or detract[s] from the dignity of the court." Carone v. Whalen, 121 F.R.D. 231, 232 (M.D.Pa.1988) (citations and quotations omitted).

Plaintiffs do not state how their motion to strike meets the standard of Rule 12(f). Indeed, they do not even assert that such material is "redundant, immaterial, impertinent, or scandalous." Fed.R.Civ.P. 12(f). Rather, they assert that the material sought to be struck is factually unsupported, "conclusory," and "speculative." Pl. Brf. at 11–12; Reply Brf. at 11–12. Although Plaintiffs couch their argument in terms of Rules 12(f) and Rule 8, it appears that Plaintiffs are attempting to use Rule 12(f) for a purpose better suited for a motion to dismiss under Rule 12(b)(6).

A motion to strike under Federal Rule 12(f) is the appropriate remedy for the elimination of redundant, immaterial, impertinent, or scandalous matter in any

pleading, and is the primary procedure for objecting to an insufficient defense.... Rule 12(f) also is designed to reinforce the requirement in Rule 8[d] that pleadings be simple, concise, and direct. However, as the cases make clear, it is neither an authorized nor a proper way to procure the dismissal of all or a part of a complaint, or a counterclaim, or to strike an opponent's affidavits. But as is true in other contexts, the technical name given to a motion challenging a pleading is of little importance inasmuch as prejudice to the nonmoving party hardly can result from treating a motion that has been inaccurately denominated a motion to strike as a motion to dismiss the complaint.

\*9 5C Wright and Miller, Fed. Prac. & Proc. Civ. (3d ed.) § 1380. Consequently, the Court shall consider the motion as one to dismiss under Rule 12(b)(6), and to the extent that paragraphs 32, 36, and 40 of the counterclaims attempt to assert claims for patent misuse, such claims shall be dismissed. Defendants' pleading is completely devoid of factual support for the allegations in the challenged paragraphs. Defendants do not identify any prior art allegedly rendering each of the patents obvious, and do not state any facts from which it can be inferred that Plaintiffs had knowledge that each of the patents were invalid or that the present lawsuit is "objectively baseless." Such bald and conclusory assertions simply fail to state a claim under the appropriate standard.

#### D. Conclusion

For the reasons above, Plaintiffs' motion is granted. The Seventh Counterclaim and the patent misuse claims contained in paragraphs 32, 36, and 40 of the counterclaims are dismissed.

Where a pleading is dismissed on Rule 12(b)(6) grounds, "a District Court must permit a curative amendment, unless an amendment would be inequitable or futile." *Alston v. Parker*, 363 F.3d 229, 235 (3d Cir.2004). Consequently, Defendants shall be granted leave to file an amended pleading. An appropriate Order accompanies this Opinion.

#### **All Citations**

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# **Tab 31**

2012 WL 6595806 Only the Westlaw citation is currently available. NOT FOR PUBLICATION United States District Court, D. New Jersey.

Brittani TIGERT, Plaintiff, v.

RANBAXY PHARMACEUTICALS, INC. et. al., Defendants.

Civil No. 12–00154 (RBK/JS). | Dec. 18, 2012.

#### **Attorneys and Law Firms**

Michael L. Rosenberg, Seeger Weiss LLP, Newark, NJ, for Plaintiff.

Eileen O. Muskett, Fox Rothschild LLP, Atlantic City, NJ, for Defendants.

#### **OPINION**

KUGLER, District Judge.

\*1 This matter comes before the Court on the motion of Medicis Pharmaceutical Corporation ("Defendant") for judgment on the Second Amended Complaint of Brittani Tigert ("Plaintiff"), pursuant to Federal Rule of Civil Procedure 12(c). Plaintiff allegedly suffered serious liver damage after taking the prescription drug Solodyn®. Plaintiff now contends that Defendant failed to adequately warn consumers of Solodyn's dangers, seeking damages under either a strict products liability or negligence theory of liability. Defendant asserts its presumptive non-liability under Texas law, which undisputedly applies to this case. Defendant further notes that both the Fifth Circuit Court of Appeals and several Texas district courts have held that the immunity exception Plaintiff seeks to invoke is preempted by federal law. Despite Defendant's request that the Court defer to the Fifth Circuit's ruling, the Court finds that the presumption against preemption obtains in this case. Accordingly, Defendant's motion for judgment on the pleadings is **DENIED**.

#### I. BACKGROUND

Plaintiff, a 21 year old college student, was prescribed Solodyn® ("Solodyn") to treat her acne. Compl. ¶ 7.3. Defendant manufactures, markets, and distributes Solodyn. *Id.* at ¶ 6.3. After allegedly filling six prescriptions for the drug, Plaintiff suffered serious liver damage and experienced liver failure. *Id.* at ¶ 7.5. Plaintiff claims that when she was originally prescribed Solodyn, the drug's packaging insert "grossly understated the risks associated" with Solodyn. *Id.* at ¶ 8.6. The actual label on the drug, however, was approved by the Food and Drug Administration ("FDA") and featured FDA-approved warnings. See *Id.* at ¶ 8.6. Plaintiff continues to receive treatment for her condition and claims that her use of Solodyn caused permanent injuries. *Id.* at ¶ 7.4.

Plaintiff now seeks damages, under either strict products liability or a negligence theory of liability, for Defendant's alleged failure to warn consumers and medical care professionals of the potential dangers of Solodyn. Plaintiff initially also brought common law claims for misrepresentation of facts, breach of implied warranty, and fraudulent concealment, but later stipulated to their dismissal.

Defendant files the present motion asserting its immunity as a matter of law. Under Texas law, defendants in "failure to warn" products liability actions are afforded a rebuttable presumption of non-liability when "the warnings or information that accompanied the product in its distribution were those approved by the United States Food and Drug Administration." Tex. Civ. Prac. & Rem.Code § 82.007(a)(1). This presumption may be rebutted by establishing that "the defendant, before or after pre-market approval ... withheld from or misrepresented to the United States Food and Drug Administration required information that was material and relevant to the performance of the product and was causally related to the claimant's injury." § 82.007(b)(1). Defendants raise § 82.007(a) (1) as an affirmative defense and contend that the § 82.007(b)(1) exception is preempted by federal law according to the Supreme Court's decision in Buckman Co. v. Plaintiff's Legal Comm., 531 U.S. 341, 121 S.Ct. 1012, 148 L.Ed.2d 854 (2001). Plaintiff urges this Court to adopt an alternative interpretation of both the Texas statute and recent case law and find no preemption.

#### II. LEGAL STANDARD

\*2 Under Fed.R.Civ.P. 12(c), a court will grant judgment on the pleadings if, on the basis of the pleadings, no material issue of fact remains and the movant is entitled to judgment

as a matter of law. See Fed.R.Civ.P. 12(c); DiCarlo v. St. Mary Hosp., 530 F.3d 255, 259 (3d Cir.2008). In reviewing 12(c) motions, the court must accept the nonmoving party's well-pleaded factual allegations as true and construe those allegations in the light most favorable to the nonmoving party. See DiCarlo, at 262–63. The court "may grant such a motion only where 'it appears beyond doubt that the plaintiff can prove no set of facts in support of his claim which would entitle him to relief." Carino v. Stefan, 376 F.3d 156, 159 (3d Cir.2004) (quoting Conley v. Gibson, 355 U.S. 41, 45–46, 78 S.Ct. 99, 2 L.Ed.2d 80 (1957)).

#### III. DISCUSSION

Plaintiff's ability to overcome Defendants' presumptive non-liability hinges on whether this Court will follow the Fifth Circuit decision in *Lofton v. McNiel Consumer & Specialty Pharmaceuticals* that § 82.007(b)(1) is preempted, or adopt the position of the Second Circuit and determine that it is not. See *Lofton*, 672 F.3d 372 (5th Cir.2012); see *Desiano v. WarnerLambert & Co.*, 467 F.3d 85 (2d Cir.2006). Defendant encourages the Court to defer to the Fifth Circuit's interpretation of *Buckman*, citing the general principle that, where possible, courts should interpret the law to avoid circuit conflicts. See Def.'s Reply Br. Further Supp. Mot. J. Pleadings ("Def.'s Reply Br.") at 3–4. Defendant further notes that the Court should defer to the Fifth Circuit because it is the regional circuit court. *Id*. at 4.

Neither party challenges the applicability of Texas law to this dispute. *See* Pl. Second Amend. Compl. at 18; Def.'s Mot. J. Pleadings at 1. As such, a choice of law analysis is unnecessary.

As a preliminary matter, this Court is not bound by the Fifth Circuit's interpretation of federal law. See e.g. Desiano, 467 F.3d at 90-91 (stating the court was not obligated to defer to a foreign circuit's views on federal law); see also Colby v. J.C. Penny Co., Inc., 811 F.2d 1119, 1123 (7th Cir.1987) (noting that neither circuit nor district courts are required to give automatic deference to the decisions of other courts of appeals). Moreover, whatever duty the Court may have had to avoid a circuit conflict is now irrelevant, as a split of authority already exists among courts who have addressed this issue. See Garcia v. Wyeth-Ayerst Labs., 385 F.3d 961 (6th Cir.2004) (holding that Michigan statute containing an immunity exception was preempted by federal law); accord Lofton, 672 F.3d at 381 (§ 82.007(b)(1) preempted by federal law absent the FDA's prior finding of fraud). But see Desiano, 467 F.3d at 98 (concluding that the Michigan immunity

exception is not prohibited through preemption); accord Yocham v. Novarties Pharmaceuticals Corp., 736 F.Supp.2d 875 (D.N.J.2010) (holding that § 82.007(b)(1) not preempted by federal law). Therefore, this Court will evaluate the question of federal preemption independently, declining to automatically defer to the Fifth Circuit's interpretation.

#### The Lofton Decision

\*3 The Fifth Circuit faced a substantially similar question to the one now before this Court in *Lofton*. The plaintiffs sued a drug manufacturer for the manufacturer's alleged failure to warn consumers of the risk of severe autoimmune allergic reactions to Motrin®. *Lofton*, 672 F.3d at 374. The drug manufacturer moved for summary judgment, asserting the Texas presumption of non-liability. *Id.* The plaintiffs attempted to overcome the presumption by arguing, pursuant to § 82.007(b)(1), that the drug manufacturer had withheld or misrepresented material information to the FDA, but the district court found that federal law preempted the state statute. *Id.* at 375. On appeal, the Fifth Circuit affirmed the district court's ruling. *Id.* at 381.

In the absence of directly on point precedent from either the United States or Texas Supreme Court, the Fifth Circuit searched for guidance in relevant Supreme Court decisions and the conflicting decisions of two circuit courts. At the time, the Supreme Court had held that traditional products liability claims were not preempted merely because a drug's warning label was approved by the FDA, See Wyeth v. Levine, 555 U.S. 555, 129 S.Ct. 1187, 173 L.Ed.2d 51 (2009), but that fraud on the agency claims, in which liability attached "solely by virtue of the FDCA disclosure requirements," were preempted by federal law. See Buckman Co. v. Plaintiff's Legal Comm., 531 U.S. 341, 121 S.Ct. 1012, 148 L.Ed.2d 854 (2001). The Lofton court first questioned whether the Texas statute fit more appropriately within the *Buckman* framework or was shielded from preemption altogether under Wyeth. Lofton, 672 F.3d 375-77. After deciding that the Buckman framework applied, the court then evaluated competing interpretations of the Supreme Court's decision. Id. at 377.

Both the Second and Sixth Circuit had encountered the question of *Buckman* preemption with a similar Michigan immunity exception<sup>2</sup> and reached divergent conclusions. The Sixth Circuit determined that the exception was impliedly preempted by *Buckman*, because the statute "inevitably conflict[ed] with the FDA's responsibility to police fraud consistently with the Agency's judgment and objectives."

Garcia, 385 F.3d at 965 (quoting Buckman, 531 U.S. at 350). Noting the applicability of concerns about judicial interference with the FDA cited in Buckman, the Sixth Circuit found that the Michigan statute was not sufficiently distinct from a fraud on the agency claim to merit differential treatment. Id. at 965–66. Consequently, the court held that unless the FDA itself had already found fraud, plaintiffs could not attempt to overcome the presumption of non-liability by invoking the "fraud-on-the-FDA" statutory exception. Id. at 967.

- The Michigan statute stated in relevant part:
  - "(5) In a product liability action against a manufacturer or seller, a product that is a drug is not defective or unreasonably dangerous, and the manufacturer or seller is not liable, if the drug was approved for safety and efficacy by the United States food and drug administration, and the drug and its labeling were in compliance with the United States food and drug administration's approval at the time the drug left the control of the manufacturer or seller ... This subsection does not apply if the defendant at any time before the event that allegedly caused the injury does any of the following:
    - (a) Intentionally withholds from or misrepresents to the United States food and drug administration information concerning the drug that is required to be submitted under the federal food, drug, and cosmetic act, and the drug would not have been approved, or the United States food and drug administration would have withdrawn approval for the drug if the information were accurately submitted." Mich. Comp. Laws Ann. § 600.2946(5) (citations omitted).

The Second Circuit, however, subscribed to a narrower interpretation of Buckman, holding that the Michigan statute was not preempted. See *Desiano*, 467 F.3d at 98. The court first found that the "presumption against preemption," which did not apply in Buckman, attached to the plaintiff's claims because they fell within the legislature's power to regulate matters of health and safety, "a sphere in which the presumption against preemption ... stands at its strongest." *Id*. at 94. The court also noted that the plaintiffs were not pursuing "fraud-on-the-FDA" claims, but rather were "asserting claims that sound in traditional state tort law." Id. The court further distinguished the matter before them from Buckman because proof of fraud against the FDA was not an actual element of the plaintiffs claim, but rather would become germane "only if a defendant company chooses to assert an affirmative defense made available by the Michigan legislature." 4 Id. at 96 (emphasis in original). Noting that "common law liability cannot be easily displaced in our federal system," the court found that the Michigan statute did not "implicate the same concerns that animated the Supreme Court's decision in Buckman" and was consequently not preempted. *Id.* at 97.

- The Second Circuit also importantly noted that the position of no preemption aligned with the pharmaceutical industries' position articulated during oral argument in *Buckman*. The pharmaceutical industry stressed the unusual nature of the claims asserted by the plaintiffs and stated that "this is a very unusual form of State law product liability action. The plaintiffs don't claim that these devices were in any way defective. There's no claim here of manufacturing defect. There's no claim here of design defect. The plaintiffs also don't claim that the surgeon who used these devices did anything wrong. There's no claim of medical malpractice." *Desiano*, 467 F.3d at 95 (quoting Oral Argument Transcript, *Buckman*, 531 U.S. 341, 121 S.Ct. 1012, 148 L.Ed.2d 854 (2000) (No. 98–1768)).
- The Court is not persuaded by this argument or by the Second Circuit's assertion that "only when proof of fraud is by itself *sufficient* to impose liability-and indeed is the sole basis of liability (as it was in *Buckman*)-does the incentive to flood the FDA appreciably escalate."

  Desiano, 467 F.3d at 97 (emphasis in original). This is a "distinction without a difference." *Yocham*, 736 F.Supp.2d at 888. As a practical matter, the concerns of flooding the FDA remain whether fraud on the agency is an essential element of the plaintiff's claim, or a procedural hurdle to overcome the presumption of non-liability. Nevertheless, the Court finds that the statute is not preempted.
- \*4 The Fifth Circuit evaluated each court's rationale and found the Second Circuit's interpretation unpersuasive. See Lofton, 672 F.3d at 379. Skirting the question of whether the presumption against preemption applied, the court reached the conclusion that "because § 82.007(b)(1) requires a Texas plaintiff to prove fraud-on-the-FDA to recover for failure to warn, this requirement invokes federal law supremacy according to Buckman." Id. The court rejected the Second Circuit's distinction between fraud on the agency as a predicate to recovery and the fraud on the agency cause of action, asserting that the distinction fails "when the statute at issue conditions recovery on 'establishing' what amounts to fraud on the agency." Id. at 380. The court adopted the Sixth Circuit's ruling on this basis, finding that "the threat of imposing state liability on a drug manufacturer for defrauding

the FDA intrude [d] on the competency of the FDA and its relationship with regulated entities." *Id*.

#### Reconsidering Lofton

The Fifth Circuit emphasized the dangers recognized in *Buckman* and their potential realization if plaintiffs were permitted to invoke § 82.007(b)(1) to overcome defendants' presumptive non-liability. Unfortunately, the court highlighted certain portions of the *Buckman* opinion to the exclusion of others. The Supreme Court indeed cautioned that state law fraud-onthe-agency claims incentivized applicants "to submit a deluge of information that the Administration neither wants nor needs, resulting in additional burdens on the FDA's evaluation of an application." *Buckman*, 531 U.S. at 351. This was not, however, the primary rationale motivating the decision.

The Supreme Court reached concerns of burdening the FDA only after determining that the presumption against preemption did not obtain in Buckman. The court contrasted fraud on the agency claims, which existed "solely by virtue of the FDCA disclosure requirements," from traditional state tort law claims, which implicated "federalism concerns and the historic primacy of state regulation of matters of health and public safety." Id. at 347-48, 353. The court further distinguished the claims in Buckman from traditional state tort law claims by noting that fraud on the agency claims served solely as a mechanism for policing the FDA. This mechanism was not only duplicative, as the FDA "has at its disposal a variety of enforcement options that allow it to make a measured response to suspected fraud upon the Administration," but also potentially troublesome as it could impose "additional burdens" on the FDA. See Id. at 349–51. This distinction is crucial because unlike traditional state tort law claims in which the plaintiffs must still establish the elements of a tort, thus regulating the interaction between the defendant and plaintiff, fraud on the agency claims regulated only the "defendant's interaction with a federal agency." Yocham, 736 F .Supp.2d at 887. The Fifth Circuit overlooked these critical differences when it failed to recognize the applicability of the presumption against preemption and expanded *Buckman* preemption to § 82.007(b)(1).

\*5 While this Court finds persuasive Defendant's argument that similar concerns of judicial oversight of the FDA manifest with § 82 .007(b)(1), these concerns were not the decisive factors in the Supreme Court preempting fraud on the agency claims. The court reached concerns of interference

only after first finding that fraud on the agency claims presented a unique circumstance in which the traditional presumption against preemption of state law did not apply. Such is not the case here. As such, the Supreme Court's narrow ruling in *Buckman* is unstable ground on which to rest a finding of preemption. Therefore, the Court finds that § 82.007(b) (1) is not preempted by federal law.

#### **Sufficiency of Plaintiff's Second Amended Complaint**

Defendant alternatively argues that if the Court declines to follow Lofton, the Court must still grant the motion for judgment on the pleadings because Plaintiff does not allege fraud with sufficient particularity pursuant to Federal Rule of Civil Procedure 9(b). Fed. R. Civ. Proc. R. 9(b) (2006). This argument was raised for the first time in Defendant's reply brief. In both the Answer and brief in support of the motion for judgment on the pleadings, Defendant contends that Plaintiff failed to allege fraud with particularity only with respect to the misrepresentation, breach of implied warranty, and fraudulent concealment claims, all of which were voluntarily dismissed. See Def.'s Answer ¶¶ 10.1–12.10; see also Def.'s Mot. J. Pleadings at 12. Consequently, the Court will decline to consider this argument. See U.S. v. Boggi, 74 F.3d 470, 478 (3d Cir.1996) (Court of appeal would not consider arguments raised in a reply brief so that appellees are not prejudiced by the lack of opportunity to respond); see also Stern v. Halligan, 158 F.3d 729, 731 n. 3 (3d Cir.1998) ("A party cannot raise issues for the first time in a reply brief."); see also D'alessandro v. Bugler Tobacco Co., 2007 WL 130798 (D.N.J. Jan. 12, 2007) (stating that a moving party may not raise new issues in a reply brief because "no sur-reply is permitted, so the opponent has no opportunity to address the new defense.")

Defendant also implies, without any supporting law, that Plaintiff's stipulation to dismissal of the misrepresentation and fraudulent concealment claims precludes her from invoking the statutory exceptions to Defendant's presumptive non-liability. The Court finds this argument unpersuasive.

#### IV. CONCLUSION

For the foregoing reasons, Defendant's motion for judgment on the pleadings pursuant to Federal Rule of Civil Procedure 12(c), is DENIED. An accompanying order shall issue today. Case 1:19-md-02875-RMB-SAK Document 1451-1 Filed 08/02/21 Page 284 of 322 Tigert v. Ranbaxy Pharmaceuticals, Inc., Not Reported in Example 2012

2012 WL 6595806

**All Citations** 

Not Reported in F.Supp.2d, 2012 WL 6595806

**End of Document** 

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**Tab 32** 

2016 WL 3708218 Only the Westlaw citation is currently available. United States District Court, D. New Jersey.

Francisco VILLEGAS, Plaintiff, v.

CORRECTIONAL MEDICAL SERVICES, INC., et al, Defendants.

Civil Action No. 14-7337 (MCA) | Filed 07/12/2016

**Attorneys and Law Firms** 

Francisco Villegas, Trenton, NJ, pro se.

#### MEMORANDUM AND ORDER

Madeline Cox Arleo, District Judge

\*1 Plaintiff Francisco Villegas, a prisoner confined at New Jersey State Prison, seeks to bring this civil action *in forma pauperis*, without prepayment of fees or security, asserting claims pursuant to 42 U.S.C. § 1983, the New Jersey Civil Rights Act, and state law. The Court previously denied without prejudice his application to proceed *in forma pauperis* ("IFP"). (ECF No. 3.) Plaintiff has resubmitted his IFP application (ECF Nos. 4-5), and the Court grants his IFP application at this time.

Federal law requires this Court to screen Plaintiff's Complaint for *sua sponte* dismissal prior to service, and to dismiss any claim if that claim fails to state a claim upon which relief may be granted under Fed. R. Civ. P. 12(b)(6) and/or to dismiss any defendant who is immune from suit. *See* 28 U.S.C. § 1915(e) (2)(B).

According to his Complaint, Plaintiff was diagnosed with Hepatitis C in 2006, and his nine count Complaint alleges violations of his rights under § 1983, the NJCRA, and state law arising Defendants' delayed and inadequate treatment of his serious medical condition. He alleges that the Defendants delayed treating his Hepatitis C for seven years, which has resulted in irreversible liver damage, and that Defendants are currently providing him with inadequate treatment for his serious medical condition. This Court has screened the

Complaint in this action for dismissal and has determined that dismissal of the entire Complaint is not warranted at this time.

The Court, however, will dismiss with prejudice the § 1983 and NJCRA claims against the NJDOC, NJSP, and the OAG, as these entities are not "persons" for purposes of § 1983 or the NJCRA. See Will v. Michigan Department of State Police, 491 U.S. 58, 64, 70-71 (1989) (holding that state is not a "person" within the meaning of Section 1983); see also Grieco v. Lanigan, No. CV 15-7881 (FLW), 2016 WL 3450808, at \*3 (D.N.J. June 17, 2016). The Court will also dismiss with prejudice the official capacity § 1983 and NJCRA claims for damages against the individual Defendants employed by the NJDOC, NJSP, and the OAG, as "officialcapacity suits 'generally represent only another way of pleading an action against an entity of which an officer is an agent.' " Hafer v. Melo, 502 U.S. 21, 25 (1991) (citing Kentucky v. Graham, 473 U.S. 159, 165 (1985)) (quoting Monell v. New York City Dept. of Social Services, 436 U.S. 658, 690, n. 55(1978)).

The Complaint also lists as a Defendant, the New Jersey Department of Public Safety and Correctional Services, which appears to be another name for the NJDOC. To the extent, this Defendant is a separate state entity, it too would be subject to dismissal because it is not a person under § 1983 or the NJCRA.

The Court will also dismiss without prejudice Counts Four and Five of the Complaint, which allege conspiracy claims brought pursuant to §§ 1983 and 1986.<sup>2</sup> Civil rights conspiracies require a "meeting of the minds," and, thus, plaintiffs must provide some factual basis to support the existence of the elements of a conspiracy, namely, agreement and concerted action. *See Startzell v. City of Philadelphia*, 533 F.3d 183, 205 (3d Cir. 2008) (citing *Adickes v. S.H. Kress & Co.*, 398 U.S. 144, 158 (1970). Here, Plaintiff has provided only conclusory allegations that Defendants engaged in a conspiracy to deprive him of his civil rights.

Section 1986 is a companion to Section 1985(3) and provides a cause of action against persons who, knowing that a violation of § 1985(3) is about to be committed and possessing the power to prevent its occurrence, fail to take action to frustrate its execution. See Rogin v. Bensalem Tp., 616 F.2d 680, 696 (3d Cir. 1980), cert, denied, 450 U.S. 1029 (1981). In turn, "Section 1985(3) permits an action to be brought by one injured by a conspiracy formed 'for the purpose of depriving, either directly or indirectly, any person or class of persons of the

equal protection of the laws, or of equal privileges and immunities under the laws." Farber v. City of Paterson, 440 F.3d 131, 134 (3d Cir. 2006) (citing 42 U.S.C. § 1985(3)). The elements of a section 1985 claim are wellestablished and Plaintiff must allege the following: "(1) a conspiracy; (2) motivated by a racial or class based discriminatory animus designed to deprive, directly or indirectly, any person or class of persons to the equal protection of the laws; (3) an act in furtherance of the conspiracy; and (4) an injury to person or property or the deprivation of any right or privilege of a citizen of the United States." Lake v. Arnold, 112 F.3d 682, 685 (3d Cir. 1997) (citing Griffin v. Breckenridge, 403 U.S. 88, 91 (1971)). "[T]ransgressions of § 1986 by definition depend on a preexisting violation of § 1985." Clark v. Clabaugh, 20 F.3d 1290, 1295 (3d Cir. 1994). In addition to establishing the existence of a Section 1985 conspiracy, a plaintiff asserting a claim under Section 1986 must demonstrate that: "(1) the defendant had actual knowledge of a § 1985 conspiracy, (2) the defendant had the power to prevent or aid in preventing the commission of a § 1985 violation, (3) the defendant neglected or refused to prevent a § 1985 conspiracy, and (4) a wrongful act was committed." Id. Here, Plaintiff has not pleaded the substantive elements of a § 1985(3) or a § 1986 conspiracy.

\*2 The Court will also dismiss without prejudice the § 1983 and NJCRA claims against Defendant Saint Francis Medical Center because Plaintiff has alleged only that this entity is "responsible for providing health care services to prisoners housed within Defendant NJSP, NJDOC" (ECF No. 1, Compl. at ¶ 5), and has not alleged sufficient facts to suggest that this entity could be considered a state actor. *See, e.g., Columbie v. CMS*, No. CIV. 11-6168 JAP, 2012 WL 1183698, at \*3 (D.N.J. Apr. 9, 2012) (dismissing St. Francis Medical Center as a non-state actor).

Finally, the Court will also dismiss without prejudice Count One of the Complaint, which alleges a state law claim for breach of contract, and alleges that Plaintiff is an intended third-party beneficiary of a contract between Defendants Correctional Medical Services ("CMS") and/or University of Medicine and Dentistry of New Jersey ("UMDNJ") and the remaining Defendants. Plaintiff appears to allege that he is an intended third-party beneficiary of the contract between Defendant CMS and/or UMDNJ and the State of New Jersey. His claim is presumably based on N.J.S.A. § 2A:15-2, which provides: "A person for whose benefit a contract is made, either simple or sealed, may sue thereon in any court ... although the consideration of the contract did not move from him." Under New Jersey law, a third-party may only enforce

a contract if it is an intended beneficiary, rather than a mere incidental beneficiary. See Rieder Communities, Inc. v. Twp. of N. Brunswick, 227 N.J. Super. 214, 546 A.2d 563, 566 (App. Div. 1988). To determine whether a third-party is an intended beneficiary, New Jersey courts look to whether the contracting parties have expressly intended for that thirdparty to "receive a benefit which might be enforced in the courts." Airmaster Sales Co. v. N. Bridge Park Co-op, Inc., 748 F.Supp. 1110, 1117-18 (D.N.J. 1990). A number of courts in this District have held that inmates do not have standing to sue on the contract between Defendant Correctional Medical Services and the State of New Jersey. See AH v. D.O.C., No. CIV. A. 08-2425 (FSH), 2008 WL 5111274, at \*5 (D.N.J. Nov. 25, 2008); Washington v. Corr. Med. Servs., No. CIV. 05-3715 (AET), 2006 WL 1210522, at \*5 (D.N.J. May 1, 2006); Allmondy. McDowell, Civ. No. 98-3733 (D.N.J. April 16, 2001); Mann v. Barbo, Civ. No. 00-2215 (D.N.J. July 24, 2001). Other than his conclusory allegation that he is an intended third-party beneficiary (ECF No. 1, Compl. at ¶ 28), Plaintiff has not provided facts in his Complaint to support an argument that the contract between CMS and/or UMDNJ and the State of New Jersey contains language that would make him an intended beneficiary with standing to sue. As a result, the Court will dismiss his breach of contract claim without prejudice at this time.

The Complaint shall otherwise proceed at this time.

IT IS therefore on this 11 day July, 2016,

**ORDERED** that Plaintiffs application to proceed *in forma* pauperis is hereby granted; and it is further

**ORDERED** that the Complaint shall be filed; and it is further

**ORDERED** that, pursuant to 28 U.S.C. § 1915(b) and for purposes of account deduction only, the Clerk shall serve a copy of this Order by regular mail upon the Attorney General of the State of New Jersey and the warden of New Jersey State Prison; and it is further

**ORDERED** that Plaintiff is assessed a filing fee of \$350.00 and shall pay the entire filing fee in the manner set forth in this Order pursuant to 28 U.S.C. § 1915(b)(1) and (2), regardless of the outcome of the litigation, meaning that if the Court dismisses the case as a result of its *sua sponte* screening, or Plaintiffs case is otherwise administratively terminated or closed, § 1915 does not suspend installment payments of the

filing fee or permit refund to the prisoner of the filing fee, or any part of it, that has already been paid; and it is further

\*3 ORDERED that pursuant to *Bruce v. Samuels*, 136 S. Ct. 627, 632 (2016), if Plaintiff owes fees for more than one court case, whether to a district or appellate court, under the Prison Litigation Reform Act (PLRA) provision governing the mandatory recoupment of filing fees, Plaintiffs monthly income is subject to a simultaneous, cumulative 20% deduction for *each* case a court has mandated a deduction under the PLRA; *i.e.*, Plaintiff would be subject to a 40% deduction if there are two such cases, a 60% deduction if there are three such cases, etc., until all fees have been paid in full; and it is further

**ORDERED** that pursuant to 28 U.S.C. § 1915(b)(2), in each month that the amount in Plaintiffs account exceeds \$10.00, the agency having custody of Plaintiff shall assess, deduct from Plaintiffs account, and forward to the Clerk of the Court payment equal to 20% of the preceding month's income credited to Plaintiffs account, in accordance with *Bruce*, until the \$350.00 filing fee is paid. Each payment shall reference the civil docket numbers of the actions to which the payment should be credited; and it is further

**ORDERED** that Plaintiff's § 1983 and NJCRA claims against the NJDOC, NJSP, and OAG are dismissed WITH PREJUDICE; the official capacity claims for damages against the individual Defendant employees of the NJDOC, NJSP, and OAG named in the Complaint are likewise dismissed WITH PREJUDICE; and it is further

**ORDERED** that the Counts Four and Five of the Complaint, which allege conspiracy claims brought pursuant to §§ 1983 and 1986, are dismissed WITHOUT PREJUDICE; and it is further

**ORDERED** that the § 1983 and NJCRA claims against Defendant Saint Francis Medical Center is dismissed WITHOUT PREJUDICE; and it is further

**ORDERED** that Count One of the Complaint, which alleges breach of contract based on Plaintiff's alleged status as a third-party beneficiary is dismissed WITHOUT PREJUDICE; and it is further

**ORDERED** that the Complaint shall otherwise PROCEED at this time; and it is further

**ORDERED** that, the Clerk shall mail to Plaintiff a transmittal letter explaining the procedure for completing Unites States Marshal ("Marshal") 285 Forms ("USM-285 Forms"); and it is further

**ORDERED** that, once the Marshal receives the USM-285 Form(s) from Plaintiff and the Marshal so alerts the Clerk, the Clerk shall issue summons in connection with each USM-285 Form that has been submitted by Plaintiff, and the Marshal shall serve summons, the Complaint and this Order to the address specified on each USM-285 Form, with all costs of service advanced by the United States<sup>3</sup>; and it is further

Alternatively, the U.S. Marshal may notify Defendant(s) that an action has been commenced and request that the defendant(s) waive personal service of a summons in accordance with Fed. R. Civ. P. 4(d).

**ORDERED** that Defendant(s) shall file and serve a responsive pleading within the time specified by Federal Rule of Civil Procedure 12; and it is further

**ORDERED** that, pursuant to 28 U.S.C. § 1915(e)(1) and § 4(a) of Appendix H of the Local Civil Rules, the Clerk shall notify Plaintiff of the opportunity to apply in writing to the assigned judge for the appointment of pro bono counsel; and it is further

**ORDERED** that, if at any time prior to the filing of a notice of appearance by Defendant(s), Plaintiff seeks the appointment of pro bono counsel or other relief, pursuant to Fed. R. Civ. P. 5(a) and (d), Plaintiff shall (1) serve a copy of the application by regular mail upon each party at his last known address and (2) file a Certificate of Service<sup>4</sup>; and it is further

- After an attorney files a notice of appearance on behalf of a Defendant, the attorney will automatically be electronically served all documents that are filed in the case.
- \*4 **ORDERED** that the Clerk of the Court shall serve Plaintiff with copies of this Memorandum and Order via regular mail.

#### **All Citations**

Not Reported in Fed. Supp., 2016 WL 3708218

Case 1.19-md-02875-RMB-SAK Document 1451-1 Filed 08/02/21 Page 289 of 322 villegas v. Correctional Medical Services, Inc., Not Reported in 1821-1 Supp. (2016)

2016 WL 3708218

**End of Document** 

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# Tab 33

#### 2019 WL 3003693

Only the Westlaw citation is currently available.
United States District Court, E.D.
Michigan, Southern Division.

Paul WEIDMAN, Raul Valentin, Erica Gomez, Perry Burton, Teresa Perry, and Roy Naasz, Individually and on behalf of all others similarly situated, Plaintiffs,

V.

#### FORD MOTOR COMPANY, Defendant.

Case No.: 18-cv-12719 | Signed 07/10/2019

#### **Attorneys and Law Firms**

Mark P. Chalos, Lieff, Cabraser, Heimann & Bernstein, Nashville, TN, Adam J. Levitt, Daniel R. Ferri, John E. Tangren, DiCello Levitt & Casey LLC, Chicago, IL, Dennis A. Lienhardt, Butzel Long, a professional corporation, Bloomfield Hills, MI, H. Clay Barnett, III, W. Daniel Miles, III, Beasley Allen Crow Methvin Portis & Miles PC, Montgomery, AL, Melvin B. Hollowell, Sharon S. Almonrode, William Kalas, E. Powell Miller, The Miller Law Firm, P.C., Rochester, MI, for Plaintiffs Paul Weidman, Raul Valentin, Erica Gomez, Perry Burton, Teresa Perry.

Adam J. Levitt, DiCello Levitt & Casey LLC, Chicago, IL, Dennis A. Lienhardt, Butzel Long, a professional corporation, Bloomfield Hills, MI, E. Powell Miller, Sharon S. Almonrode, William Kalas, The Miller Law Firm, P.C., Rochester, MI, Mark P. Chalos, Lieff, Cabraser, Heimann & Bernstein, Nashville, TN, W. Daniel Miles, III, Beasley Allen Crow Methvin Portis & Miles PC, Montgomery, AL, for Plaintiff Roy Naasz.

Randall William Edwards, O'Melveny and Myers LLP, San Francisco, CA, Scott Michael Hammack, O'Melveny & Myers LLP, Washington, DC, Stephanie A. Douglas, Bush Seyferth & Paige, Troy, MI, for Defendant.

## OPINION AND ORDER GRANTING IN PART AND DENYING IN PART DEFENDANT'S MOTION

### TO DISMISS CONSOLIDATED CLASS ACTION COMPLAINT [#35]

Hon. Gershwin A. Drain, United States District Court Judge

#### I. INTRODUCTION

\*1 Presently before the Court is the Defendant, Ford Motor Company's, Motion to Dismiss Consolidated Class Action Complaint, filed on December 18, 2018. Plaintiffs filed their Response in Opposition on January 23, 2019. Defendant filed a Reply in support of its Motion to Dismiss on February 6, 2019. Upon review of the parties' submissions, the Court concludes that oral argument will not aid in the disposition of this matter. Accordingly, the Court will resolve the Defendant's Motion for Summary Judgment on the briefs. See E.D. Mich. L.R. 7.1(f)(2). For the reasons that follow, the Court will grant in part and deny in part Defendant's Motion to Dismiss Consolidated Class Action Complaint.

#### II. FACTUAL BACKGROUND

Plaintiffs are six individuals from five different states who, at varying times between 2015 through 2017, purchased a Ford F-150 truck. Plaintiffs allege that each of these vehicles contains a defective front brake master cylinder that places it at risk of suddenly and unexpectedly losing braking ability. Plaintiffs assert that the master cylinders in all the F-150 trucks, model years 2013 through 2018, have a "defective sealing mechanism that is inadequate to prevent brake fluid ... from leaking," causing reduced or lost braking ability. Compl. at §§ 4-5. Plaintiffs Paul Weidman, Roy Naasz, and Teresa Perry allege that they experienced some loss of braking force while driving. Specifically, Plaintiff Weidman maintains that his brakes failed within five months of purchasing his truck. Plaintiff Perry's brakes failed with less than 20,000 miles on her truck and Plaintiff Naasz's brakes failed while he was trying to slow down for a freeway off-ramp. In each case, Ford technicians diagnosed the problem as a failed master cylinder.

Plaintiffs further allege that Ford's pre-sale knowledge of the master cylinder defect is evident from internal documents that it provided to the National Highway Traffic Safety Administration. For example, on June 16, 2015, a Ford engineer sent an email stating "Master Cylinder leaks are getting a lot of attention at Ford." Compl. § 76. Plaintiffs further assert that there are an exceptionally high number of consumer complaints regarding the master cylinder defect, beginning with the model year 2013.

Ford admitted the existence of the master cylinder defect in a safety recall. However, Plaintiffs complain that the recall was inadequate because it only covered F-150s from model years 2013 through 2014. The recall was also inadequate because it simply provided for the replacement of the defective master cylinder with another defective master cylinder.

Plaintiffs seek to certify a nationwide class of all "current or former owners and/or lessees" of model year 2013 through 2018 Ford F-150 trucks under federal law, as well as seek to certify, on multiple claims, separate Alabama, California, Florida, Georgia and Texas state classes for vehicles purchased or leased in those states.

#### III. LAW & ANALYSIS

#### A. Standard of Review

Federal Rule of Civil Procedure 12(b)(6) allows the court to make an assessment as to whether the plaintiff has stated a claim upon which relief may be granted. See Fed. R. Civ. P. 12(b)(6). "Federal Rule of Civil Procedure 8(a)(2) requires only 'a short and plain statement of the claim showing that the pleader is entitled to relief,' in order to 'give the defendant fair notice of what the ... claim is and the grounds upon which it rests." Bell Atlantic Corp. v. Twombly, 550 U.S. 544, 555, 127 S.Ct. 1955, 167 L.Ed.2d 929 (2007) (citing Conley v. Gibson, 355 U.S. 41, 47, 78 S.Ct. 99, 2 L.Ed.2d 80 (1957)). Even though the complaint need not contain "detailed" factual allegations, its "factual allegations must be enough to raise a right to relief above the speculative level on the assumption that all of the allegations in the complaint are true." Ass'n of Cleveland Fire Fighters v. City of Cleveland, 502 F.3d 545, 548 (6th Cir. 2007) (quoting *Bell Atlantic*, 550 U.S. at 555, 127 S.Ct. 1955).

\*2 The court must construe the complaint in favor of the plaintiff, accept the allegations of the complaint as true, and determine whether plaintiff's factual allegations present plausible claims. To survive a Rule 12(b)(6) motion to dismiss, plaintiff's pleading for relief must provide "more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do." *Id.* (citations and quotations omitted). "[T]he tenet that a court must accept as true all of the allegations contained in a complaint is inapplicable to legal conclusions." *Ashcroft v. Iqbal*, 556 U.S. 662, 129 S. Ct. 1937, 1949, 173 L.Ed.2d 868 (2009). "Nor does a complaint suffice if it tenders 'naked assertion[s]'

devoid of 'further factual enhancement.' " *Id.* "[A] complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.' " *Id.* The plausibility standard requires "more than a sheer possibility that a defendant has acted unlawfully." *Id.* "[W]here the well-pleaded facts do not permit the court to infer more than the mere possibility of misconduct, the complaint has alleged—but it has not 'show[n]'—'that the pleader is entitled to relief.' " *Id.* at 1950.

The district court generally reviews only the allegations set forth in the complaint in determining whether to grant a Rule 12(b)(6) motion to dismiss, however "matters of public record, orders, items appearing in the record of the case, and exhibits attached to the complaint, also may be taken into account. *Amini v. Oberlin College*, 259 F. 3d 493, 502 (6th Cir. 2001). Documents attached to a defendant's "motion to dismiss are considered part of the pleadings if they are referred to in the plaintiff's complaint and are central to her claim." *Id.* 

#### **B.** Breach of Express Warranty

Defendant argues that Plaintiffs' allegations show that Ford fully complied with the terms of its Limited Warranty. The Complaint alleges Ford breached its express warranty to repair defective parts because when the Plaintiffs presented their vehicles for repair of the master cylinder, Ford installed the same defective master cylinder. Compl. §§ 202, 318. Defendant argues that Plaintiffs failure to allege that any problems have reoccurred is fatal to their express warranty claim. Plaintiffs rely on two out-of-circuit cases in support of their position. *See Benkle v. Ford Motor Co.*, No. SA CV 16-1569-DOC, 2017 WL 9486154, 2017 U.S. Dist. LEXIS 222317 (C.D. Cal. Dec. 22, 2017); *Gertz v. Toyota Motor Corp.*, No. CV 10-1089, 2011 WL 13142144, 2011 U.S. Dist. LEXIS 158165 (C.D. Cal. Apr. 28, 2011).

However, Plaintiffs' claims are governed by Alabama and Texas law. Plaintiff has provided no authority from these jurisdictions demonstrating that replacing an allegedly defective part with the same part amounts to a breach of an express warranty. See Rhodes v. Gen. Motors Corp., Chevrolet Div., 621 So.2d 945, 948 (Ala. 1993) (finding no breach of express warranty where "it is undisputed that each time [plaintiffs] brought the vehicle in for repairs, it was repaired" and plaintiffs "produced no evidence that the ... repair failed to remedy the car's transmission problem."); Am. Med. Oxygen

Sales Corp. v. Inova Labs, Inc., No. 1:14-CV-278-LY, 2015 WL 12532766, 2015 U.S. Dist. LEXIS 181369 (W.D. Tex. Oct. 19, 2015) (finding no breach of express warranty where plaintiff "has not alleged that [defendant] has failed to provide such repairs or replacements when requested.").

Ford's Limited Warranty states that "[n]othing in this warranty should be construed as requiring defective parts to be replaced with parts of a different type or design than the original part, so long as the vehicle functions properly with the replacement part." Plaintiffs have not alleged that they experienced any problems subsequent to the replacement of the master cylinder. Plaintiffs rely on *Benkle*, but that case involves California law and allegations that the "replacement [parts] are substantially certain to fail." *Benkle*, 2017 WL 9486154, at \*12, 2017 U.S. Dist. LEXIS 222317, at \*37. Unlike the *Benkle* plaintiffs, Plaintiffs do not allege the replacement parts are substantially certain to fail.

Plaintiffs further assert that Ford's argument is precluded by the "essential purpose" provision of the UCC. Plaintiffs maintain that since the warranty explicitly states its purpose is "to remedy" any "defects that result in vehicle part malfunction or failure during the warranty period[,]" by replacing the defective master cylinders with the same defective part, Ford failed to remedy the brake system defect. As such, Ford's repair failed in its essential purpose under both Texas and Alabama law. Ala. Code § 7-2-719 ("Where circumstances cause an exclusive or limited remedy to fail of its essential purpose, remedy may be had as provided in this title."); Tex. Bus. & Com. Code Ann. § 2.719 (same). However, this argument appears to suffer from the same problem. Namely, Plaintiffs fail to allege that the problems with the brake system reoccurred.

\*3 Ford also argues that Plaintiff Perry's express warranty claim fails for the additional reason that she does not allege that she provided Ford with notice of the defects. Under Texas law, a claim for breach of express warranty requires a plaintiff to have provided pre-suit notice of the alleged breach to both the seller and remote manufacturer of the defective product. *McKay v. Novartis Pharm. Corp.*, 751 F.3d 694, 706-07 (5th Cir. 2014).

Here, Plaintiff Perry only alleges that Plaintiff Weidman notified Ford of the alleged defect "on behalf of the other Class Members." Compl. ¶ 319. Plaintiff argues this is enough because Texas's notice requirement is to be liberally construed citing to *Vintage Homes, Inc. v. Coldiron*, 585 S.W.2d 886,

889 (Tex. Ct. App. 1979). However, in *Vintage Homes*, the defendant became aware of the defective mobile home because the buyer contacted the dealer, who in turn contacted the defendant. *Id.* at 887. The defendant then sent a repairman to inspect the unit. *Id.* at 887.

Plaintiff does not similarly allege that she took any steps to put Ford on notice of the defect with her vehicle's brake system. Nor does she offer any authority suggesting that U.S. Tire-Tech, Inc. v. Boeran, B.V., 110 S.W.3d 194, 201-02 (Tex. App. 2003), authority provided by Defendant, has been overturned. In U.S. Tire-Tech, the Texas Court of Appeal held that "[t]he manufacturer must be made aware of a problem with a particular product purchased by a particular buyer." Id. For this additional reason, Plaintiff Perry's breach of express warranty claim fails.

Based on the foregoing, counts 3 and 15 will be dismissed.

#### C. Breach of Implied Warranty of Merchantability

Ford next raises several reasons that the Court should dismiss Plaintiffs' breach of implied warranty of merchantability claims. First, Ford argues that the Court should dismiss the implied warranty of merchantability claims for lack of privity as to Plaintiffs Weidman (AL), Burton (GA), and Naasz (CA) (counts 4, 11, and 22), because the laws of those states preclude a plaintiff from suing for breach of an implied warranty of merchantability unless the warranted product was purchased directly from the warrantor. Plaintiffs Weidman, Burton and Naasz allege that they purchased their trucks from independent Ford dealers, thus these Plaintiffs are not in privity with Ford and their implied warranty claims must fail. Williams v. Yamaha Motor Corp., U.S.A., No. CV 13-05066 BRO (VBKx), 2015 WL 2375906, at \*4, 2015 U.S. Dist. LEXIS 193825, at \*14-17 (C.D. Cal. Jan. 7, 2015); Rampey v. Novartis Consumer Health, Inc., 867 So. 2d 1079, 1087 (Ala. 2003) ("[A] claim for breach of an implied warranty is not available against a manufacturer who was not involved in the transaction pursuant to which the complaining party purchased the product."); Keaton v. A.B.C. Drug Co., 266 Ga. 385, 467 S.E.2d 558, 561 (Ga. 1996) (same).

Plaintiffs acknowledge the privity requirement, but maintain there are exceptions to the privity rule, including where a plaintiff is the intended third-party beneficiary of an agreement between the manufacturer and the retailer. See In re MyFord Touch Consumer Litig., 46 F. Supp.3d 936,

983-84 (N.D. Cal. 2014). The *MyFord Touch* court held that "the third-party beneficiary exception remains viable under California law." *Id.* at 984. The court also noted that the Ninth Circuit's decision in *Clemens v. DaimlerChrysler Corp.*, 534 F.3d 1017, 1024 (9th Cir. 2008), a case relied on by Defendant, did not clearly hold that the third-party beneficiary exception is unavailable under California law. Upon consideration of the parties' arguments, the Court is not inclined to dismiss Plaintiffs Burton's and Naasz's breach of implied warranty claims based on a lack of privity because the they have identified cases that have recognized the exception for the privity requirement. *Id., see also Terrill v. Electrolux Home Prod., Inc.*, 753 F. Supp. 2d 1272, 1288 (S.D. Ga. 2010).

\*4 However, Plaintiff Weidman has failed to identify any case law from Alabama suggesting an exception to the privity requirement. Therefore, Plaintiff Weidman's implied warranty claim must be dismissed because there is an absence of authority contrary to the holding in *Rampey v. Novartis Consumer Health, Inc.*, 867 So. 2d 1079, 1087 (Ala. 2003)("[A] claim for breach of an implied warranty is not available against a manufacturer who was not involved in the transaction pursuant to which the complaining party purchased the product."). Count 4 is dismissed.

Defendant further asserts that Plaintiff Naasz's claim for breach of the implied warranty of merchantability under California's Song-Beverly Act fails because that law's protections apply only to new vehicles. Thus, because Plaintiff Naasz leased his vehicle for two years prior to purchasing it, Defendant argues he has no claim under the Song-Beverly Act. However, as a lessee, Naasz has a viable breach of implied warranty claim under the Act. See Song-Beverly Act. Cal. Code § 1791(a)(defining "consumer goods" to include a lease of a new product); see also D.L. Edmonson Selective Serv. Inc. v. LCW Auto. Corp., 689 F. Supp.2d 1226, 1236 (C.D. Cal. 2010)(a "lessee has the same rights against the manufacturer that the lessee would have 'if the goods had been purchased by the lessee.' "). Contrary to Defendant's argument, the Song-Beverly Act's protections apply to leased vehicles.

However, Defendant also argues that all of the implied warranty claims fail because the alleged "defect" referenced in the Complaint is insufficient to render the vehicles unmerchantable. Defendant argues that Plaintiffs have not alleged that their vehicles are unfit for their ordinary purpose of providing transportation. Plaintiff Naasz only alleges that

he experienced a single instance of reduced braking power and that he sought and received a repair. He does not allege any further experiences that have prevented the vehicle from providing transportation. He does not allege that the purported master cylinder defect prevents him from using his vehicle. Therefore, Defendant argues Plaintiff Naasz cannot maintain his implied warranty claim for this separate reason. *See Am. Suzuki Motor Corp. v. Superior Court*, 37 Cal. App. 4th 1291, 1296, 44 Cal.Rptr.2d 526 (1995).

Plaintiff Naasz counters that the implied warranty of merchantability is breached when an alleged defect affects the "drivability, safety, and usefulness" of a vehicle. *Amin v. Mercedes-Benz USA, LLC*, 301 F. Supp.3d 1277, 1287 (N.D. Ga. 2018). However, the *Amin* plaintiffs alleged that their cars HVAC system had a defect that caused "accumulation of mold ... caus[ing] the Vehicles passenger cabin to be unbearable and thus, unusable for its intended purpose[,]" and that the system was known to secrete toxins that are harmful to humans and animals. *Id.* at 1288. In the instant case, Naasz does not allege his vehicle cannot brake nor that he is unable to use his vehicle. It would appear that Naasz's implied warranty claims fail for this reason. Counts 21 and 22 are likewise dismissed.

Defendant further argues that Plaintiff Barton has failed to allege that he ever experienced any issues with the operation of his vehicle. Defendant argues that the overwhelming majority of courts recognize that a product that never manifests an alleged defect cannot serve as the basis for a claim for breach of the implied warranty of merchantability. *See Briehl v. Gen. Motors Corp.*, 172 F.3d 623, 627-29 (8th Cir. 1999) (collecting cases); *Hines v. Mercedes-Benz USA*, LLC, 358 F. Supp.2d 1222, 1233 (N.D. Ga. 2005).

\*5 Plaintiffs counter that the fact Plaintiff Burton's brakes have not yet failed does not affect the viability of his implied warranty claim. However, the cases Plaintiff cites either involve manifested defects, *Willis Mining, Inc. v. Noggle*, 235 Ga.App. 747, 509 S.E.2d 731 (Ga. Ct. App. 1998); *Sloan v. Gen. Motors LLC*, 287 F. Supp.3d 840 (N.D. Cal. 2018), or did not apply Georgia law, *In re Gen. Motors LLC Ignition Switch Litig.*, 257 F.Supp.3d 372, 426 (S.D.N.Y. 2017). Plaintiff has not provided controlling authority that the Georgia courts would permit an implied warranty claim to proceed without allegations that the vehicle was inoperable or unusable. Thus, Count 11 is also dismissed.

Lastly, Defendant also maintains that similar to her express warranty claim, Plaintiff Perry failed to provide the required pre-suit notice for her implied warranty claim. The notice requirement applies equally to her implied warranty claims. *Martin v. Home Depot, U.S.A., Inc.*, 369 F. Supp.2d 887, 893 (W.D. Tex. 2005). As such, Plaintiff Perry's implied warranty claim (Count 16) is similarly dismissed.

#### D. Magnuson-Moss Warranty Act

Defendant next argues that since Plaintiffs have failed to allege any viable breach of warranty claims, their claims under the MMWA (count 1) also fail. Defendant is correct that if the Court finds Plaintiffs have failed to adequately plead express and implied warranty claims, their claim under the MMWA also fails. *Gill v. Bluebird Wanderlodge*, No. 5:02-CV-328-2(CAR), 2004 WL 5311477, at \*4 (M.D. Ga. Feb. 4, 2004); *Zea v. Ford Motor Co.*, No. H-14-3290, 2017 WL 979067, at \*2 (S.D. Tex. Mar. 10, 2017); *Chase v. Kawasaki Motors Corp., U.S.A.*, 140 F. Supp.2d 1280, 1291 (M.D. Ala. 2001); *Clemens v. Daimler Chrysler Corp.*, 534 F.3d 1017, 1022 n.3 (9th Cir. 2008). Count 1 is therefore dismissed.

#### E. Fraud

Defendant also argues that Plaintiffs' fraud based claims fail because they do not sufficiently allege Ford's knowledge of the defect. Defendant also complains that Plaintiffs fail to allege the requisite particularity concerning how they relied upon any statement or omission by Ford.

Ford maintains that Weidman's demand letter was insufficient to provide pre-suit notice under Alabama's Deceptive Trade Practices Act ("ADTPA"). The Act requires that a consumer provide a potential defendant with "a written demand for relief, identifying the claimant and reasonably describing the unfair or deceptive act or practice relied upon and the injury suffered." Ala. Code § 8-19-10(e).

As an initial matter, Plaintiff argues that the demand provision does not apply here because the act states that pre-suit notice "shall not apply if the prospective respondent does not maintain a place of business or does not keep assets within the state." Ala. Code § 9-19-10(e). Because Ford neither maintains a place of business nor keeps assets in Alabama, pre-suit notice is not required. Ford does not address this

argument other than to complain that these allegations are not in the Complaint.

Even if Defendant is correct that pre-suit notice is required, Weidman's letter satisfied the requirements of the statute. It described Weidman's experience of "a loss of brake function involving the master cylinder and brake booster" in his 2017 F-150 truck, and asserted that Ford violated ADTPA Section § 8-19-5(27) by selling F-150 trucks with knowledge that they were materially defective and by knowingly concealing this material information. The letter explained the substance of Weidman's claims, including that Ford failed to disclose "a uniform defect" in its F-150 trucks: a brake system "prone to lose hydraulic pressure and fail during normal operation" due to a faulty master cylinder. The letter also made a written demand for relief.

\*6 Similarly, Plaintiff Burton satisfied the Georgia Fair Business Practices Act's notice requirement. "The notice requirement of [the FBPA] is to be liberally construed, and the sufficiency of notice is a question for the court." Amin v. Mercedes-Benz USA, LLC, 301 F. Supp. 3d 1277, 1292 (N.D. Ga. 2018). In the class action context, notice from one consumer expressing intent to bring representative claims on behalf of others satisfies the FBPA's notice requirement for all putative claimants, named or otherwise. *Id.* (holding that plaintiff who did not send separate demand letter could "rely on the pre-suit demand sent by" another plaintiff individually and "on behalf of all others similarly situated."); see also Schorr v. Countrywide Home Loans, Inc., 287 Ga. 570, 697 S.E.2d 827, 829 (Ga. 2010) (demand from named plaintiffs satisfies FBPA requirement for unnamed class members); In re Arby's Rest. Grp. Inc. Litig., No. 1:17-cv-0514-AT, 1:17cv-1035-AT, 1:17-mi-55555-AT, 2018 WL 2128441, at \*19 (N.D. Ga. Mar. 5, 2018) (permitting one plaintiff to "rely on the pre-suit demand" sent by other plaintiffs on behalf of "all others similarly situated.")

Moreover, Plaintiffs have adequately alleged Ford's pre-sale knowledge contrary to Defendant's assertion. The Complaint includes allegations showing Ford's pre-sale knowledge of the brake system defect through "pre-release evaluation and testing; repair data, replacement part sales data; early consumer complaints made directly to Ford, collected by NHTSA, testing done in response to those complaints, aggregate data from Ford dealers; and other internal sources." Compl., ¶¶ 83-105. Construed liberally, these allegations are sufficient to demonstrate Ford's knowledge of the defect in the brake system.

Contrary to Defendant's argument, Plaintiffs also adequately allege reliance. Plaintiffs have alleged that they relied to their detriment on Ford's omissions concerning the brake system defect when making the decision to purchase or lease their F-150s. Compl., ¶ 193-94, 224-25,242-43, 252-53, 271-72, 290-91, 309-10, 340-41, 365-66, 380, 422. Plaintiffs further allege that they would not have purchased, or would not have paid as much for, their F-150s had they known of the brake system defect. Id.

Ford argues that Plaintiffs Valentin, Gomez and Burton's fraudulent omission claims also fail pursuant to the economic loss doctrine. Contrary to Defendant's argument, neither Florida nor Georgia applies the economic loss doctrine to bar claims involving fraudulent inducement.

In Tiara Condo. Ass'n, Inc. v. Marsh & McLennan Cos., Inc., 110 So.3d 399, 406-07 (Fla. 2013), the Supreme Court of Florida addressed the need to limit the "over-expansion of the economic loss rule," expressly holding that the economic loss rule does not apply to claims based on fraudulent inducement or negligent misrepresentation. Id. at 406. With respect to fraudulent inducement, the court cited to its previous opinion in HTP, Ltd. v. Lineas Aeras Costarricenses, S.A., 685 So. 2d 1238, 1239 (Fla. 1996), in which it held that "fraud in the inducement is an independent tort and is not barred by the economic loss rule." *Id.* Following *Tiara*, federal courts have refused to apply the economic loss doctrine to bar fraudulent concealment claims under Florida law. See MyFord Touch, 46 F. Supp. 3d at 965; *In re Volkswagon Timing Chain Prod. Liab*. Litig., No. 16-2765, 2017 WL 1902160, at \*18 (D.N.J. May 8, 2017). Here, Plaintiffs' fraudulent omission claim falls within the fraudulent inducement exception recognized in *Tiara* and MyFord Touch, as these claims stem from Ford's intent to induce the Florida Plaintiffs into purchasing their F-150s by concealing the Brake System Defect. See Tiara, 110 So. 3d at 406; MyFord Touch, 46 F. Supp. 3d at 965.

The economic loss doctrine is likewise no bar to the Georgia Plaintiff's fraudulent omission and Fair Business Practices Act claims, as Georgia does not recognize the economic loss rule for claims arising from fraudulent inducement. See James v. Terex USA, LLC, No. CV 516-60, 2017 WL 2126596, at \*1-2 (S.D. Ga. May 16, 2017) ("Georgia courts ... have repeatedly recognized an exception to the economic loss rule for fraudulent inducement claims"); Holloman v. D.R. Horton, Inc., 241 Ga.App. 141, 524 S.E.2d 790, 797 (Ga. Ct. App. 1999) ("The economic loss rule is inapplicable in the presence of passive concealment or fraud.")

#### F. Unjust Enrichment

Lastly, Defendant argues that Plaintiffs' unjust enrichment claims (counts 6, 9,13,18 and 24) fail because Ford's Limited Warranty covers the same subject matter. Plaintiff counters that it is well established in the Sixth Circuit that a plaintiff may plead unjust enrichment in the alternative. However, Defendant acknowledges the existence of the limited warranty. While Plaintiff argues that it would be improper at the pleading stage to dismiss this claim because Defendant may dispute the allegation in a subsequent stage of the proceeding, Defendant does not appear likely to do that. Because Ford "admits to the existence of a valid contract such that whether a contract exists is not at issue for the factfinder[,]" Plaintiffs' unjust enrichment claims fail. See Terry Barr Sales Agency, Inc. v. All-Lock Co., 96 F.3d 174, 182 (6th Cir. 1996). Counts 6, 9, 13, 18 and 24 should be dismissed.

#### IV. CONCLUSION

Accordingly, for the reasons articulated above, Defendant Ford Motor Company's Motion to Dismiss Consolidated Class Action Complaint [#35] is GRANTED IN PART and DENIED IN PART.

Counts 1, 3, 4, 6, 9, 11, 13, 15, 16, 18, 21, 22 and 24 are dismissed.

Counts 2, 5, 7, 8, 10, 12, 14, 17, 19, 20 and 23 remain.

SO ORDERED.

#### **All Citations**

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# Tab 34

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# IN RE: ZANTAC (RANITIDINE) PRODUCTS LIABILITY LITIGATION

MDL NO. 2924 | 20-MD-2924 | Signed 06/30/2021

ORDER GRANTING IN PART AND DENYING IN PART THE DEFENDANTS' OMNIBUS MOTION TO DISMISS AND/OR STRIKE CONSOLIDATED MEDICAL MONITORING CLASS ACTION COMPLAINT AND CONSOLIDATED AMENDED CONSUMER ECONOMIC LOSS CLASS ACTION COMPLAINT

### ROBIN L. ROSENBERG, UNITED STATES DISTRICT JUDGE

\*1 This matter is before the Court on the Defendants' Omnibus Motion to Dismiss and/or Strike Consolidated Medical Monitoring Class Action Complaint and Consolidated Amended Consumer Class Action Complaint [DE 3116] (the "Motion"). The Court held a hearing on the Motion to Dismiss on June 3, 2021 (the "Hearing"). The Court has carefully considered the Motion, the Response [DE 3429], the Reply [DE 3508], the arguments that the parties made during the Hearing, and the record, and is otherwise fully advised in the premises. For the reasons set forth below, the Defendants' Motion to Dismiss is **GRANTED IN PART AND DENIED IN PART**, and the Plaintiffs' claims are **DISMISSED IN PART** as more fully set forth in this Order. The Court's dismissal is with leave to amend.

#### I. Factual Background

A court must accept a plaintiff's factual allegations as true at the motion-to-dismiss stage. *West v. Warden*, 869 F.3d 1289, 1296 (11th Cir. 2017) ("When considering a motion to dismiss, we accept as true the facts as set forth

in the complaint and draw all reasonable inferences in the plaintiff's favor.") (quotation marks omitted). Plaintiff's have set forth their factual allegations in three "master" complaints: the Amended Master Personal Injury Complaint ("AMPIC"); the Consolidated Amended Consumer Economic Loss Class Action Complaint ("ELC"); and the Consolidated Medical Monitoring Class Action Complaint ("MMC") (collectively, the "Master Complaints"). DE 2759, 2835, 2832-1. Unless otherwise noted, all citations will be made to the redacted versions of the Master Complaints.

This case concerns the pharmaceutical product Zantac and its generic forms, which are widely sold as heartburn and gastric treatments. The molecule in question—ranitidine—is the active ingredient in both Zantac and its generic forms.

Zantac has been sold since the early 1980s, first by prescription and later as an over-the-counter ("OTC") medication. In 1983, the U.S. Food and Drug Administration ("FDA") approved the sale of prescription Zantac. AMPIC ¶ 240. GlaxoSmithKline ("GSK") first developed and patented Zantac. *Id.* ¶ 239. Zantac was a blockbuster—the first prescription drug in history to reach \$1 billion in sales. *Id.* ¶ 240.

GSK entered into a joint venture with Warner-Lambert in 1993 to develop an OTC form of Zantac. Id. ¶ 233. Beginning in 1995, the FDA approved the sale of various forms of OTC Zantac. Id. ¶¶ 233, 237. The joint venture between GSK and Warner-Lambert ended in 1998, with Warner-Lambert retaining control over the sale of OTC Zantac in the United States and GSK retaining control over the sale of prescription Zantac in the United States. Id. ¶ 243. Pfizer acquired Warner-Lambert in 2000 and took control of the sale of OTC Zantac in the United States. Id. ¶ 245. The right to sell OTC Zantac in the United States later passed to Boehringer Ingelheim Pharmaceuticals and then to Sanofi. Id. ¶¶ 249–50, 253–55. When the patents on prescription and OTC Zantac expired, numerous generic drug manufacturers began to produce generic ranitidine products in prescription and OTC forms. Id. ¶¶ 260-62.

\*2 Scientific studies have demonstrated that ranitidine can transform into a cancer-causing molecule called N-nitrosodimethylamine ("NDMA"), which is part of a carcinogenic group of compounds called N-nitrosamines. *Id.* ¶¶ 348, 359, 365, 367. Studies have shown that these compounds increase the risk of cancer in humans and animals. *Id.* ¶¶ 398–404. The FDA, the Environmental Protection Agency, and the International Agency for Research on Cancer

consider NDMA to be a probable human carcinogen. *Id.* ¶¶ 275, 279. The FDA has set the acceptable daily intake level for NDMA at 96 nanograms. *Id.* ¶¶ 302.

Valisure LLC and ValisureRX LLC, a pharmacy and testing laboratory, filed a Citizen Petition on September 9, 2019, calling for the recall of all ranitidine products due to high levels of NDMA in the products. *Id.* ¶ 322. The FDA issued a statement on September 13 warning that some ranitidine products may contain NDMA. *Id.* ¶ 323. On November 1, the FDA announced that testing had revealed the presence of NDMA in ranitidine products. *Id.* ¶ 333. The FDA recommended that drug manufacturers recall ranitidine products with NDMA levels above the acceptable daily intake level. *Id.* Five months later, on April 1, 2020, the FDA requested the voluntary withdrawal of all ranitidine products from the market. *Id.* ¶ 338.

#### II. Procedural Background

After the discovery that ranitidine products may contain NDMA, plaintiffs across the country began initiating lawsuits related to their purchase and/or use of the products. On February 6, 2020, the United States Judicial Panel on Multidistrict Litigation created this multi-district litigation ("MDL") pursuant to 28 U.S.C. § 1407 for all pretrial purposes and ordered federal lawsuits for personal injury and economic damages from the purchase and/or use of ranitidine products to be transferred to the undersigned. DE 1. Since that time, approximately 1,400 plaintiffs have filed lawsuits in, or had their lawsuits transferred to, the United States District Court for the Southern District of Florida. In addition, this Court has created a Census Registry where tens of thousands of claimants who have not filed lawsuits have registered their claims. See DE 547.

Plaintiffs filed their first Master Complaints on June 22, 2020. DE 887, 888, 889. In those Master Complaints, Plaintiffs contended that the ranitidine molecule is unstable, breaks down into NDMA, and has caused thousands of consumers of ranitidine products to develop various forms of cancer. DE 887 ¶¶ 1, 6, 19. They alleged that "a single pill of ranitidine can contain quantities of NDMA that are hundreds of times higher" than the FDA's allowable limit. *Id.* ¶ 4. The Plaintiffs pursued federal claims and state claims under the laws of all 50 U.S. states, Puerto Rico, and the District of Columbia. *See generally* DE 889.

The Court has entered numerous Pretrial Orders to assist in the management of this MDL. In Pretrial Order #36, the Court set a schedule for the filing and briefing of the first round of motions to dismiss under Rule 12 directed to the Master Complaints. DE 1346. The various defendants filed motions to dismiss.

On December 31, 2020, the Court granted the Defendants' Motions to Dismiss and dismissed the Master Complaints without prejudice and with leave to amend. DE 2515. The Court also struck all allegations of physical injury and medical monitoring from the Consolidated Consumer Class Action Complaint, while permitting the plaintiffs to seek leave of Court for an alternative pleading to allege their class physical injury and/or medical monitoring claims.

\*3 Following an amendment to Pretrial Order #36, Plaintiffs filed the AMPIC on February 8, 2021. DE 2759. After the Court granted a two-week extension of time [DE 2720], Plaintiffs filed the MMC [DE 2832-1] and the ELC [DE 2835] on February 22, 2021. In Pretrial Order #61, the Court set a schedule for the filing and briefing of the second round of motions to dismiss under Rule 12 directed to the Master Complaints. DE 2968. The Defendants filed the Motion to Dismiss addressed herein pursuant to that schedule.

#### **III. The Master Complaints**

### A. The Consolidated Medical Monitoring Class Action Complaint

Fifty-two named Plaintiffs bring the MMC on behalf of themselves and the various classes established in the MMC. MMC ¶¶ 93-144. The Plaintiffs purchased and used ranitidine products in fourteen jurisdictions. Each Plaintiff alleges that he or she purchased and used ranitidine products during an approximate timeframe.

Arizona, California, Colorado, District of Columbia, Florida, Indiana, Maryland, Missouri, Montana, Nevada, Ohio, Pennsylvania, Utah, and West Virginia.

There are five categories of classes: (1) Brand Manufacturer Prescription Medical Monitoring Classes; (2) Brand Manufacturer OTC Medical Monitoring Classes; (3) Generic Prescription Medical Monitoring Classes; (4) Store-Brand Medical Monitoring Classes; and (5) Store-Brand Manufacturer Medical Monitoring Classes. Within each category, there are state- and Defendant-specific classes.

For example, within the third category (Generic Prescription Medical Monitoring Classes), several named Plaintiffs bring claims against Defendant Amneal on behalf of themselves and eleven state-specific "Amneal Prescription Medical Monitoring Classes." *Id.* ¶ 998. Within the fourth category (Store-Brand Medical Monitoring Classes), five named Plaintiffs bring claims against Defendant CVS on behalf of themselves and four state-specific "CVS Medical Monitoring Classes." *Id.* ¶ 1004. The various classes are comprised of individuals who purchased and used one of the Defendants' ranitidine products while residing in a particular state, and who have not been diagnosed with a Subject Cancer.<sup>3</sup>

Plaintiffs define "Subject Cancers" as "[t]hose cancers includ[ing] serious and potentially fatal bladder, breast, colorectal/intestinal, esophageal, gastric, kidney, liver, lung, pancreatic, and prostate cancers." MMC at 3.

The Defendants named in the MMC are "entities that designed, manufactured, marketed, distributed, labeled, packaged, handled, stored, and/or sold Zantac or generic Ranitidine-Containing Products." *Id.* ¶ 6. The Plaintiffs categorized the Defendants into three groups: (1) Brand Manufacturer Defendants (Prescription and OTC); (2) Generic Prescription Manufacturer Defendants and/or Store-Brand Manufacturer Defendants; and (3) Store-Brand Defendants. The MMC alleges 638 counts against the various Defendants. <sup>4</sup> Each count falls within one of five general causes of action: (1) Failure to Warn through Warnings and Precautions; (2) Failure to Warn through Proper Expiration Dates; (3) Failure to Warn Consumers through the FDA; (4) Negligent Product Containers; and (5) Negligent Storage and Transportation.

While the MMC lists 640 total counts, there is no Count 222 or Count 223.

## **B.** The Consolidated Amended Consumer Economic Loss Class Action Complaint

One hundred and eighty named Plaintiffs bring the ELC on behalf of themselves and all others similarly situated. Each Plaintiff asserts that he or she purchased and/or used a ranitidine product during an approximate timeframe.

\*4 The Plaintiffs bring the action in their individual capacities and on behalf of numerous classes pursuant to Rule 23. The Plaintiffs bring state class actions under various state laws stemming from the Defendants' sale of prescription-strength ranitidine for approximately

forty states.<sup>5</sup> Additionally, the Plaintiffs bring state class actions under approximately forty-three states' laws for the Defendants' sale of OTC ranitidine.

The Plaintiffs have brought a varying number of statelaw counts against each Defendant.

The Defendants named in the ELC are entities that "designed, manufactured, marketed, distributed, labeled, packaged, handled, stored and/or sold Zantac or generic Ranitidine-Containing Products." ELC ¶ 1. The Defendants are categorized into three groups: (1) Brand Manufacturer Defendants (Prescription and OTC); (2) Generic Prescription Manufacturer and/or Store-Brand Manufacturer Defendants; and (3) Store-Brand Defendants. The ELC alleges 1,675 counts against the Defendants. The Plaintiffs bring claims for violation of various state consumer protection statutes, common-law unjust enrichment, common-law breach of quasi-contract, and breach of implied warranty.

## IV. Summary of the Parties' Arguments and the Court's Rulings

## A. The Consolidated Medical Monitoring Class Action Complaint

The Defendants move to dismiss and/or strike the MMC. They contend that Indiana and Montana do not recognize medical monitoring claims, and additionally, that the Plaintiffs fail to plausibly plead several required elements for medical monitoring that are common across jurisdictions. The Defendants also contend that the Plaintiffs fail to plead their claims of negligence and strict liability. Finally, the Defendants argue that the MMC violates the Eleventh Circuit's rule against claim splitting.

The Plaintiffs respond that medical monitoring is an available remedy in Indiana and a cause of action in Montana. Additionally, the Plaintiffs cite allegations in the MMC that, in their view, plausibly demonstrate each medical monitoring element that the Defendants challenge. The Plaintiffs also cite allegations in the MMC to demonstrate that they plausibly plead their negligence and strict liability claims. Lastly, the Plaintiffs respond that the MMC does not constitute claim splitting, since the Plaintiffs complied with the Court's order (and the Defendants' request) that they allege their class physical injury and/or medical monitoring claims in an alternative pleading.

The Court concludes that the Indiana Supreme Court would recognize medical monitoring as an available remedy, but that the Montana Supreme Court would not recognize medical monitoring as a cause of action. Separately, the Plaintiffs have failed to plausibly plead required elements for medical monitoring. The Plaintiffs have plausibly pled some of their negligence and strict liability claims, but the Court need not address every claim, as certain claims are dismissed with prejudice on grounds of pre-emption through other orders. Finally, the Defendants' claim splitting argument is premature. Given the foregoing, the Court dismisses Plaintiffs' Montana medical monitoring claims (Counts 134-137) with prejudice, and dismisses all remaining Counts in the MMC without prejudice and with leave to amend consistent with this Order.

### B. The Consolidated Amended Consumer Economic Loss Class Action Complaint

The Defendants argue that the ELC remains a shotgun pleading, and that the Plaintiffs still lack Article III standing because they have not alleged an injury-in-fact. Additionally, the Plaintiffs' claims related to prescription ranitidine should be dismissed under the learned intermediary doctrine. Furthermore, many of the ELC's state-law claims are barred pursuant to state consumer protection safe harbors, or relatedly, because the Defendants' FDA-approved labels were presumptively valid. Finally, the Plaintiffs fail to state claims for unjust enrichment.

\*5 The Plaintiffs respond that the ELC is not a shotgun pleading because the Plaintiffs addressed the shotgun deficiencies that the Court identified in the prior version of the ELC. The Plaintiffs also have Article III standing because they suffered economic injury-in-fact. The Court should not dismiss the Plaintiffs' prescription-based claims pursuant to the learned intermediary doctrine, in part because it is premature to determine the doctrine's applicability. Further, the Defendants' safe-harbor and FDA labeling arguments lack specificity and are inapplicable because the Plaintiffs allege that the Defendants' product labels violated both state and federal law. Finally, the Plaintiffs have stated a claim for unjust enrichment, since they allege that they conferred a benefit on the Defendants due to misrepresentations.

The Court concludes that the ELC is not a shotgun pleading, and the Plaintiffs have Article III standing because they allege that they suffered economic injury. The Plaintiffs' prescription-based claims lack allegations that are relevant to the learned intermediary doctrine. The Defendants'

arguments related to state safe harbors, FDA labeling, and unjust enrichment are inadequately briefed for the Court to reach a conclusion at this juncture. Given the foregoing, the Court dismisses the Plaintiffs' prescription-based claims (Counts 2-71 and 409-1062) without prejudice and with leave to amend consistent with this Order.

#### V. Standard of Review

#### A. Rule 12(b)(1)

Federal courts are courts of limited jurisdiction. "[B]ecause a federal court is powerless to act beyond its statutory grant of subject matter jurisdiction, a court must zealously insure that jurisdiction exists over a case, and should itself raise the question of subject matter jurisdiction at any point in the litigation where a doubt about jurisdiction arises." *Smith v. GTE Corp.*, 236 F.3d 1292, 1299 (11th Cir. 2001).

#### B. Rule 12(b)(6)

A court may grant a motion to dismiss a pleading if the pleading fails to state a claim upon which relief can be granted. Fed. R. Civ. P. 12(b)(6). A Rule 12(b)(6) motion to dismiss should be granted only when the pleading fails to contain "enough facts to state a claim to relief that is plausible on its face." Bell Atl. Corp. v. Twombly, 550 U.S. 544, 570, 127 S.Ct. 1955, 167 L.Ed.2d 929 (2007). "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." Ashcroft v. Igbal, 556 U.S. 662, 678, 129 S.Ct. 1937, 173 L.Ed.2d 868 (2009). The pleading must contain more than labels, conclusions, a formulaic recitation of the elements of a cause of action, and naked assertions devoid of further factual enhancement. Id. The "[f]actual allegations must be enough to raise a right to relief above the speculative level." *Twombly*, 550 U.S. at 555, 127 S.Ct. 1955; see also Igbal, 556 U.S. at 678, 129 S.Ct. 1937 (explaining that the plausibility standard "asks for more than a sheer possibility that a defendant has acted unlawfully").

A court ruling on a motion to dismiss accepts the well-pled factual allegations as true and views the facts in the light most favorable to the plaintiff. *Jones v. Fransen*, 857 F.3d 843, 850 (11th Cir. 2017). But the court need not accept as true allegations upon information and belief that lack sufficient facts to make the allegations plausible. *Mann v. Palmer*, 713 F.3d 1306, 1315 (11th Cir. 2013) (citing *Twombly*, 550 U.S. at

551, 557, 127 S.Ct. 1955); see also In re Darvocet, Darvon, & Propoxyphene Prods. Liab. Litig., 756 F.3d 917, 931 (6th Cir. 2014) ("The mere fact that someone believes something to be true does not create a plausible inference that it is true."). The court also need not accept legal conclusions couched as factual allegations. Diverse Power, Inc. v. City of LaGrange, Ga., 934 F.3d 1270, 1273 (11th Cir. 2019). "Under Rule 12(b) (6), dismissal is proper when, on the basis of a dispositive issue of law, no construction of the factual allegations will support the cause of action." Allen v. USAA Cas. Ins. Co., 790 F.3d 1274, 1278 (11th Cir. 2015) (quotation marks omitted).

#### VI. Analysis of the Defendants' Motion to Dismiss

\*6 The Motion raises several separate legal issues. For each issue, the Court reviews the parties' arguments, the relevant allegations, and the relevant law before providing its analysis and conclusion.

#### A. Issues Raised in the MMC

#### 1. Medical Monitoring Claims in Montana and Indiana

#### a. Arguments and Allegations

The Defendants argue that the Plaintiffs' Indiana medical monitoring claims should be dismissed. Indiana state and federal courts have held that medical monitoring is not a cognizable claim. DE 3116 at 20 (citing *Hunt v. Am. Wood Preservers Inst.*, No. IP 02-0389-C-M/S, 2002 WL 34447541, at \*1 (S.D. Ind. July 31, 2002), and *Johnson v. Abbott Labs.*, Nos. 06C01-0203-PL-89, 06C01-0206-CT-243, 2004 WL 3245947, at \*6 (Ind. Cir. Ct. Dec. 31, 2004)). Although an Indiana federal court recognized medical monitoring damages in *Allgood v. General Motors Corp.*, No. 102CV1077DFHTAB, 2005 WL 2218371 (S.D. Ind. Sept. 12, 2005), it did so only for nuisance claims, which are not alleged in this case. DE 3116 at 20. Nuisance claims are fundamentally different than the negligence and strict liability claims alleged in the MMC. DE 3508 at 10.

The Defendants also argue that the Plaintiffs' Montana medical monitoring claims should be dismissed. Only one Montana trial court case, *Lamping v. American Home Products.*, *Inc.*, No. DV-97-85786, 2000 WL 35751402, 2000 Mont. Dist. LEXIS 2580 (Mont. Dist. Feb. 02, 2000), has recognized medical monitoring. DE 3116 at 20. *Lamping* is

more than twenty years old, is unpublished, has not been acknowledged by other Montana courts, and only recognized medical monitoring on that case's specific facts. *Id.* The Eleventh Circuit has said that state trial court opinions are not authoritative for purposes of an *Erie* analysis, and that is particularly true here, where no Montana case post-*Lamping* has acknowledged medical monitoring as a cause of action under Montana law. DE 3508 at 11 (citing *Mesa Air Grp., Inc. v. Delta Air Lines, Inc.*, 573 F.3d 1124, 1131 n.8 (11th Cir. 2009)).

The Plaintiffs first argue that Indiana recognizes medical monitoring damages. DE 3429 at 29. In Gray v. Westinghouse Electric. Corp., 624 N.E.2d 49 (Ind. Ct. App. 1993), the Indiana Court of Appeals recognized that a plaintiff could obtain medical monitoring despite the absence of a present physical injury. DE 3429 at 29. This Court is bound by *Gray* given that there is no persuasive evidence suggesting that the Indiana Supreme Court would decline to follow *Gray. Id.* That the plaintiffs in *Gray* alleged nuisance, rather than negligence, is of no consequence, as courts in other jurisdictions have recognized medical monitoring damages for both torts, or have acknowledged that medical monitoring is compensable under "traditional tort theories of recovery." Id. at 29-30 (citing Meyer ex rel. Coplin v. Fluor Corp., 220 S.W.3d 712, 714 (Mo. 2007), Exxon Mobil Corp. v. Albright, 433 Md. 303, 71 A.3d 30, 77 (2013), and Potter v. Firestone Tire & Rubber Co., 6 Cal.4th 965, 25 Cal.Rptr.2d 550, 863 P.2d 795, 823 (1993)). Gray is also consistent with Indiana caselaw permitting plaintiffs to recover for all harms proximately caused by a defendant's tortious conduct, including future medical expenses. Id. at 30. The Defendants' reliance on Hunt and Johnson does not command a different result. Id. Hunt is a two-paragraph opinion that contains no analysis or caselaw, and merely concludes that medical monitoring claims are not cognizable in Indiana. Id. The Plaintiffs, however, seek medical monitoring as a remedy. Id. Johnson is an unreported trial court opinion that is also void of analysis. Id.

\*7 The Plaintiffs also argue that Montana recognizes medical monitoring as a cause of action. *Lamping* is well reasoned, has never been rejected through another Montana case, and has been recognized by other courts as reflecting Montana's medical monitoring law. *Id.* at 31. The case warrants even greater weight because Montana does not have an intermediate appellate court. *Id.* Moreover, *Lamping* is like the instant case, for it involved drugs that caused a high risk of serious heart valve disease. *Id.* Similarly, the Plaintiffs here

allege that because of their exposure to dangerous levels of NDMA, they have a significantly increased risk of developing serious and potentially fatal cancers. *Id.* 

#### b. Law on *Erie* Prediction

A federal court sitting in diversity must apply state substantive law. Erie R. Co. v. Tompkins, 304 U.S. 64, 78, 58 S.Ct. 817, 82 L.Ed. 1188 (1938). Where the highest state court has spoken on a topic, the federal court must follow its rule. Molinos Valle Del Cibao, C. por A. v. Lama, 633 F.3d 1330, 1348 (11th Cir. 2011). Where the highest state court has not spoken on the topic, the federal court must follow the decisions of intermediate appellate courts unless persuasive evidence demonstrates that the highest court would conclude otherwise. *Id.* If there is no explicit state law on an issue, "a federal court attempting to forecast state law must consider whatever might lend it insight, including 'relevant state precedents, analogous decisions, considered dicta, scholarly works, and any other reliable data tending convincingly to show how the highest court in the state would decide the issue at hand.' " Guideone Elite Ins. Co. v. Old Cutler Presbyterian Church, Inc., 420 F.3d 1317, 1326 n.5 (11th Cir. 2005) (quoting McKenna v. Ortho Pharm. Corp., 622 F.2d 657, 663 (3d Cir. 1980)). "It is not the function of federal courts to expand state tort doctrine in novel directions absent state authority suggesting the propriety of doing so." Douglas Asphalt Co. v. OORE, Inc., 657 F.3d 1146, 1154 (11th Cir. 2011).

#### c. Analysis and Conclusion

The Plaintiffs seek medical monitoring damages for their Indiana negligence claims. DE 3429 at 30. They allege medical monitoring as an independent cause of action in Montana. *Id.* at 31. The highest courts in Indiana and Montana have not addressed whether medical monitoring is a form of damages or an independent cause of action, respectively. The Court must therefore make *Erie* predictions for those jurisdictions.

<u>Indiana</u>: At least one Indiana appellate court and one federal district court have recognized medical monitoring as a form of damages. In *Gray*, property owners near a dump alleged nuisance claims against a company that worked with independent contractors to dispose of toxic chemicals, including polychlorinated biphenyls ("PCB"). 624 N.E.2d

at 52. The property owners alleged that the defendant-company knew the chemicals were poisonous, and that damage to the owners' properties was likely. The owners sought compensation for property damage and medical monitoring. After the trial court dismissed their claims on a motion to dismiss, the owners appealed. Indiana's Court of Appeals reversed and remanded in part, concluding that under Indiana's nuisance statute, the plaintiff needed to plead only a "situation [that] is injurious to health ... so as to interfere with comfortable enjoyment of life or property." *Id.* at 54. The court held that one plaintiff did so:

Taken as true, Griffin's allegations that his property is unmarketable and his health is at risk due to PCB contamination are sufficient to sustain a nuisance claim. We think it is reasonable to believe that a substantial financial loss, combined with whatever health risks and consternation Griffin may have suffered due to the possible contamination of his property with a carcinogen, would cause physical discomfort. Griffin's proof of these allegations will determine whether a nuisance in fact exists and the damages to which he is entitled.

\*8 *Id*.

By reversing the dismissal of the owners' claim for medical monitoring damages, the Court of Appeals implicitly recognized the availability of such damages in Indiana. The Southern District of Indiana acknowledged that point in *Allgood*, stating: "If medical monitoring were not an available remedy under these circumstances ... the Gray court could have affirmed the trial court to the extent it had dismissed that request for relief." 2005 WL 2218371, at \*7. The court in Allgood also clarified that "[t]he Gray court did not treat medical monitoring as a cause of action, but simply as one form of relief that could be available under the traditional common law tort of nuisance." Id. Based on its review of *Gray*, the *Allgood* court predicted that Indiana courts would recognize a claim for medical monitoring damages for nuisance claims. The court, however, declined to articulate the precise elements necessary to obtain medical monitoring damages.

This Court predicts that the Indiana Supreme Court would recognize medical monitoring as a form of damages for negligence claims. Since *Gray* is an Indiana appellate court decision, the Court must follow its recognition of medical monitoring damages absent persuasive evidence that the Indiana Supreme Court would conclude otherwise. The Defendants have not presented such evidence.

While the Defendants argue that *Gray* and *Allgood* only recognize medical monitoring damages for nuisance claims, the Court does not construe those cases so narrowly. In Allgood, the court stated that that "[i]f plaintiffs are able to prove the elements of a recognized tort such as nuisance, then the court will need to craft jury instructions to provide more specific guidance as to available remedies." *Id.* (emphasis added). *Allgood* thus contemplated medical monitoring damages for torts beyond just nuisance, and negligence certainly qualifies as a recognized tort. This reading is consistent with other jurisdictions which have acknowledged that medical monitoring relief can be sought for both nuisance and negligence claims or that medical monitoring is a compensable item of damage under traditional tort theories of recovery. See, e.g., Meyer, 220 S.W.3d at 714 (recognizing medical monitoring as a form of relief where the plaintiff alleged negligence and nuisance, among other claims); see also Potter, 863 P.2d at 823 (medical monitoring is a "compensable item of damage when liability is established under traditional tort theories of recovery").

*Hunt* and *Johnson* do not persuade the Court. Unlike *Gray*, neither is an Indiana appellate court decision. Moreover, whereas Gray and Allgood contain detailed analyses of the plaintiffs' medical monitoring claims, Hunt and Johnson do not. In *Hunt*, the Southern District of Indiana granted a motion to dismiss the plaintiffs' medical monitoring claim and stated, without explanation or citations, that "such a claim is not cognizable in the State of Indiana." 2002 WL 34447541, at \*1. In Johnson, the Indiana Circuit Court denied plaintiffs' motion for class certification, in part because the plaintiffs' request for a medical monitoring class did not satisfy the predominance requirement for class certification. 2004 WL 3245947, at \*6. The court merely cited *Hunt* and stated that "Indiana does not recognize medical monitoring as a cause of action." Id. The lack of analysis in these cases is inadequate to overcome the Indiana Court of Appeals' decision in *Gray*. This is especially true of *Johnson*, which addresses whether Indiana recognizes medical monitoring as a cause of action, rather than whether medical monitoring is an available remedy.

\*9 Montana: The Defendants correctly note that the Court lacks guidance from the Montana Supreme Court regarding medical monitoring, and that only one state trial court opinion—*Lamping*—has recognized a medical monitoring claim.<sup>6</sup> In *Lamping*, the plaintiffs alleged a cause of action for medical monitoring due to taking prescription appetite-suppression drugs—commonly referred to as "fen/phen"

drugs—manufactured and sold by the defendant. 2000 WL 35751402, at \*————, 2000 Mont. Dist. LEXIS 2580, at \*1-2. Following FDA approval, the drugs were voluntarily withdrawn from the market after reports linked the drugs to heart valve abnormalities. The plaintiffs acknowledged that the Montana Supreme Court had not recognized medical monitoring absent proof of present injury, but urged the trial court to do so. The *Lamping* court concluded that Montana recognized medical monitoring as an independent cause of action, on that case's specific facts. *Id.* at \*——, 2000 Mont. Dist. LEXIS 2580, at \*14.

### 6 Montana does not have an intermediate appellate court.

It is not this Court's role to expand state tort law absent the propriety of doing so. Douglas Asphalt, 657 F.3d at 1154; see Guarino v. Wyeth, LLC, 719 F.3d 1245, 1251 (11th Cir. 2013) ("[C]onsiderations of comity and federalism counsel that [federal courts] proceed gingerly when venturing into unchartered waters of state substantive law."). Notwithstanding the Plaintiffs' reliance on Lamping, the Court does not believe that the opinion supports expanding Montana law in the manner that the Plaintiffs suggest; to conclude otherwise would run counter to Eleventh Circuit guidance. See Mesa Air Grp., 573 F.3d at 1131 n.8 (11th Cir. 2009) ("On no interpretation of *Erie* of which we are aware may a decision by a state trial court be credited as determining the law of the state."). The Defendants' reasoning is more persuasive, including that the Court lacks any relevant guidance from the Montana Supreme Court, and that no Montana trial court has cited Lamping since it was issued more than twenty years ago.

Given the foregoing, Defendants' Motion is denied as to the Plaintiffs' Indiana medical monitoring claims but granted as to the Plaintiffs' Montana medical monitoring claims, which are dismissed with prejudice.

#### 2. Plausibility as to Medical Monitoring Claims

#### a. Arguments and Allegations

The Defendants argue that the Plaintiffs fail to plausibly allege facts supporting several elements of medical monitoring claims that are common across multiple jurisdictions. DE 3116 at 21.

First, the Plaintiffs fail to allege any exposure to a hazardous substance, since no Plaintiff plausibly alleges that the

ranitidine he or she took actually contained NDMA. Id. at 21-23. The Plaintiffs instead allege that because they consumed ranitidine, and the testing of some ranitidine products at various times revealed NDMA, the Plaintiffs must have been exposed to NDMA. DE 3508 at 11. That chain of inferences is inadequate to plausibly plead exposure to NDMA. Id. Further, the mere risk that ranitidine products might have contained NDMA is insufficient. DE 3116 at 23. Even if the Plaintiffs did plausibly allege some exposure, they neither allege a threshold level of exposure that places them at an increased risk of developing a Subject Cancer, nor that any Plaintiff's exposure exceeded that threshold. DE 3116 at 23. By failing to allege a threshold level of exposure, the Plaintiffs essentially argue that any level of exposure to NDMA is sufficient to obtain medical monitoring. DE 3508 at 12. And to the extent that the Plaintiffs rely on the FDA's daily allowable limit of 96 nanograms of NDMA, that regulatory threshold is too low and would lead to a monitoring program of unlimited scale. Id. (citing Riva v. Pepsico, Inc., 82 F. Supp. 3d 1045 (N.D. Cal. 2015)).

Second, the Plaintiffs fail to plead that diagnostic testing exists that would make the early detection of any Subject Cancer possible, since they merely allege that their proposed medical monitoring regime would include "baseline tests and diagnostic examinations that will assist in early detection." *Id.* at 24 (quoting MMC ¶ 1043).

\*10 Third, the Plaintiffs fail to plead that their proposed medical monitoring regime differs from routine examinations that they would normally undergo as members of the public. *Id.* at 25-26. The Plaintiffs' allegation that their proposed regime "is not generally given to the public at large" is insufficient, and courts in multiple jurisdictions have dismissed medical monitoring claims containing such a formulaic recitation of this required element. *Id.* at 26.

The Plaintiffs argue that whether medical monitoring is an appropriate remedy is a fact-intensive question requiring expert testimony, and one that should not be decided on a Rule 12 motion. DE 3429 at 24. Moreover, the Plaintiffs plausibly allege exposure to NDMA through years of ingesting ranitidine, which contained levels of NDMA many multiples beyond the FDA's allowable limit. *Id.* at 25, 27. Regarding diagnostic testing, the Plaintiffs satisfy the element by alleging that they require monitoring that includes "baseline tests and periodic diagnostic examinations." *Id.* at 26 (citing MMC ¶¶ 978, 980). The Court must accept this allegation as true. *Id.* The Plaintiffs also plausibly allege a monitoring

regime that is different from routine examinations, since they allege that their injuries "require specialized testing ... that is not generally given to the public at large," and which is "different from that normally recommended in the absence of exposure to this risk of harm." *Id.* (citing MMC ¶ 979). The Court must also accept those allegations as true. *Id.* Rule 8 does not require the detail that the Defendants suggest is necessary to plausibly plead the various medical monitoring elements, particularly when expert testimony is needed. *Id.* at 26-27. At this procedural juncture, the Plaintiffs need not allege a "threshold level" of NDMA exposure that creates an increased risk of the Subject Cancers, specify which diagnostic tests allow for early detection of those cancers, or explain how their proposed monitoring regime differs from what is given to the public at large. *Id.* at 26.

#### b. Law on Medical Monitoring

Medical monitoring claims are non-traditional torts, through which individuals "seek to recover the anticipated costs of long-term diagnostic testing necessary to detect latent diseases that may develop as a result of tortious exposure." *In re Nat'l Hockey League Players' Concussion Inj. Litig.*, 327 F.R.D. 245, 259-60 (D. Minn. 2018) (quotation marks omitted). Medical monitoring claims "evolved from the realization that widely recognized tort law concepts premised upon a present physical injury are ill-equipped to deal with cases involving latent injury." *Id.* at 260 (quotation marks omitted). "[A]n action for monitoring seeks to recover only the quantifiable costs of periodic medical examinations necessary to detect the onset of physical harm ...." *In re Paoli R.R. Yard PCB Litig.*, 916 F.2d 829, 850 (3d Cir. 1990).

The law of medical monitoring varies across jurisdictions, with some requiring a showing of manifest physical injury, some requiring subcellular or subclinical injury, and others not requiring any present physical injury. *Nat'l Hockey League*, 327 F.R.D. at 260. The Plaintiffs here seek medical monitoring in states where they allege that proof of present physical injury is not required: Arizona, California, Colorado, Florida, District of Columbia, Indiana, Maryland, Missouri, Montana, Nevada, Ohio, Pennsylvania, Utah, and West Virginia. MMC at 43. The elements to obtain medical monitoring under Florida law illustrate what some of these jurisdictions require:

\*11 (1) exposure greater than normal background levels; (2) to a proven hazardous substance; (3) caused by the

defendant's negligence; (4) as a proximate result of the exposure, plaintiff has a significantly increased risk of contracting a serious latent disease; (5) a monitoring procedure exists that makes the early detection of the disease possible; (6) the prescribed monitoring regime is different from that normally recommended in the absence of the exposure; and (7) the prescribed monitoring regime is reasonably necessary according to contemporary scientific principles.

Petito v. A.H. Robins Co., Inc., 750 So. 2d 103, 106-07 (Fla.App. 3 Dist. 1999).

For reasons discussed earlier, Plaintiffs' Montana medical monitoring claims are dismissed with prejudice.

Yet among these states, the elements differ in nuanced ways. For example, some states require that testing procedures exist to detect diseases early, while others do not. *Compare id.* at 106 (requiring that "a monitoring procedure exists that makes the early detection of the disease possible"), with Nat'l Hockey League, 327 F.R.D. at 263 (citing Meyer, 220 S.W.3d at 712, and Burns v. Jaquays Min. Corp., 156 Ariz. 375, 752 P.2d 28 (1987), to note that Missouri and Arizona do not require that procedures exist).

#### c. Analysis and Conclusion

No Exposure: Defendants first assert that the Plaintiffs allege no exposure at all to NDMA. DE 3116 at 22-23. The Plaintiffs respond that they plausibly allege exposure, because each Plaintiff ingested or consumed ranitidine products that contained NDMA at levels many times above the FDA-allowable limit. DE 3429 at 25.

The Court concludes that the Plaintiffs have plausibly alleged at least some exposure to NDMA. Each paragraph identifying the named Plaintiffs alleges the timeframes during which they used ranitidine. MMC ¶¶ 93-144. Next, the Plaintiffs allege that NDMA is a known carcinogen, as determined by several agencies and health authorities and supported by various studies. *Id.* ¶¶ 185-229. The Plaintiffs then allege that testing revealed the presence of NDMA in ranitidine products, which in turn led to voluntary recalls. *Id.* ¶¶ 230-49. The Plaintiffs further allege that ranitidine degrades to form excessive levels of NDMA by breaking down in the human body and upon exposure to heat, moisture, and/or time. *Id.* ¶¶ 250-304. The Plaintiffs later allege that they "ingested Ranitidine-Containing Products at various times," and that "unbeknownst to the Plaintiffs, [the Ranitidine-Containing

Products] transformed into dangerous levels of NDMA." *Id.* ¶¶ 975-76. Collectively, the Plaintiffs' allegations create a reasonable inference that they were exposed to NDMA.

Significantly Increased Risk: The Defendants argue that, even if the Plaintiffs have alleged some exposure to NDMA, they have not alleged that their exposure was so significant that medical monitoring is warranted. Although the Plaintiffs disagree and argue that their allegations are sufficient, the parties agree that the Plaintiffs are not entitled to medical monitoring for just any exposure; they agree that the Plaintiffs' exposure to NDMA must have been significant. E.g., MMC ¶ 978; DE 3429 at 24 ("The injury is plaintiff's significantly increased risk of disease ...."). In some states, the requirement for a significant exposure is an express element of the medical monitoring claim. Petito, 750 So. 2d at 106 (requiring a plaintiff to plead a "significantly increased risk of contracting a serious latent disease"). In other states, the requirement for a significant exposure exists in the form of a reasonable treating physician's diagnosis. Hansen v. Mountain Fuel Supply Co., 858 P.2d 970, 980 (Utah 1993) (requiring a plaintiff to show that because of an exposure to a toxic substance, "a reasonable physician would prescribe for her or him a monitoring regime"); Cook v. Rockwell Int'l Corp., 755 F. Supp. 1468, 1477 (D. Colo. 1991) (requiring a plaintiff to show that because of an exposure, "periodic diagnostic medical examinations" are reasonably necessary). Regardless of some variations in state law as to the level of exposure required to state a claim, the parties nevertheless agree that the Plaintiffs must allege a significant increase in their risk of cancer—a risk significant enough that a treating physician would prescribe a monitoring regime.

\*12 The Defendants' plausibility challenge—that the Plaintiffs have failed to allege a significant increase in their risk of cancer—raises two distinct questions. First, pursuant to the Plaintiffs' allegations, how much NDMA<sup>8</sup> must a Plaintiff be exposed to before the Plaintiff has a significantly increased risk of cancer? Second, how much NDMA exposure have the Plaintiffs alleged? In arguing that the Plaintiffs have failed to plausibly plead the answer to both questions, the Defendants cite to *Riva v. Pepsico, Inc.*, 82 F. Supp. 3d 1045 (N.D. Cal. 2015).

At the Hearing, the Plaintiffs clarified that while the MMC references epidemiological studies on ranitidine that do not focus on NDMA, they are relying upon exposure to NDMA to establish their claim for medical monitoring. Hearing Tr. at 213-14.

In *Riva*, the trial court concluded that the plaintiffs had adequately alleged that a certain chemical was a dangerous carcinogen. *Id.* at 1058. The problem, however, was that while the plaintiffs had alleged *how much* exposure to the chemical would result in cancer in animals, the plaintiffs had failed to adequately plead how much exposure would result in cancer in humans and how much exposure the plaintiffs had received. *Id.* at 1060. Here, the Court concludes that, like *Riva*, the Plaintiffs have adequately alleged that NDMA is a dangerous carcinogen, but, also like *Riva*, the Plaintiffs have failed to clearly plead just *how much* exposure the Plaintiffs received and how much exposure is needed to warrant the remedy of medical monitoring. The Plaintiffs' response to *Riva* is illuminating on these points.

The Plaintiffs distinguish *Riva* by arguing that, unlike the plaintiff in *Riva*, their complaint is specific. DE 3429 at 28. To demonstrate the specificity of their allegations, the Plaintiffs aver:

The MMC alleges that exposure to NDMA above 96 ng is unacceptable and increases the risk of cancer, that one ranitidine dose exposes the user to over 3000 ng of NDMA, that doses of NDMA even lower than that significantly increase the risk of cancer, that certain Defendants' testing showed NDMA in all batches of ranitidine, and that MM Plaintiffs took therapeutic doses of ranitidine for years.

Id. The Court analyzes this response phrase-by-phrase. First, the Court construes the Plaintiffs' position to be that the level of exposure to NDMA needed to warrant the remedy of medical monitoring could be as low as 96 ng of NDMA but is, in any event, no greater than 3,000 ng. Second, the Court construes the Plaintiffs' position to be that each ranitidine dose gives the consumer at least 3,000 ng of NDMA. Third and finally, the Plaintiffs describe the frequency of doses by each Plaintiff as "therapeutic doses." The Court addresses each of these topics in turn before turning to the level of specificity the Court requires in any amended MMC.

The Plaintiffs dispute whether they must allege a "threshold exposure level," a concept discussed by the *Riva* court. The Court's focus is not on whether the Plaintiffs have alleged a threshold exposure, but rather whether the Plaintiffs have plausibly alleged an undisputed element of medical monitoring—a substantial increase in the risk of disease.

The Amount of NDMA Needed to Significantly Increase the Risk of Cancer

If the Plaintiffs' position is that 3,000 ng of NDMA is the amount necessary to significantly increase a Plaintiff's risk of cancer, the Plaintiffs should clearly allege this. The Plaintiffs' response quoted above contains no citation to the MMC for this proposition. True, the Plaintiffs have clearly alleged that the consumption of 96 ng each day, for seventy years, will result in a .001% increase in the risk of cancer. MMC ¶ 210. But by the Court's math, that would mean a Plaintiff consumed not 96 ng, but 2,452,800 ng of NDMA, albeit over the course of an entire lifetime. Relatedly, if the Plaintiffs equate a .001% increased risk with a significantly increased risk, then the Plaintiffs should clearly make that argument. The Court is unable, however, to find any allegation in the MMC from which the Court could infer that a single dose of NDMA, be it 96 ng or 3,000 ng, is equated to a substantial increase in the risk of cancer. Instead, the scientific studies that the Plaintiffs rely upon study lifetime diet habits and then conclude, based upon a lifetime of eating or not eating NDMA-rich foods, the relative risk of a consumer's cancer. If the Plaintiffs' position is that the Court may infer, from those studies, that a single exposure to 3,000 ng results in a significantly increased risk of cancer, the Plaintiffs should make that argument and allege this with greater clarity.

\*13 Based upon the Court's review of the MMC, the Court believes that the more likely basis for the Plaintiffs' position is that a 3,000 ng exposure to NDMA, frequently administered, would result in a significant increase in the risk of cancer. The Court is unable to analyze that position, however, without more information.

To explain, the Plaintiffs allege that every human being consumes NDMA through eating, drinking, and even breathing. *E.g.*, MMC ¶252 (NDMA in drinking water); ¶185 n.35<sup>10</sup> (NDMA in air and food). Indeed, the NDMA studies upon which the Plaintiffs rely find a large variance in the amount of NDMA that each human being consumes on a daily basis. For example, the Plaintiffs' study at footnote 71 found daily NDMA consumption levels in cases as low as 200 ng but as high as 510 ng. The study at footnote 72 found levels as low as 130 ng but as high as 191 ng. The study at footnote 73 found levels as low as 6 ng but as high as 179 ng. <sup>11</sup> The Court does not know the Plaintiffs' position on how much NDMA a typical Plaintiff consumes (outside of ranitidine consumption)

because the Court is unable to locate any allegation to that effect, but this is a number that matters.

10 The Court considers the Plaintiffs' footnotes, which cite to government documents and scientific studies, to have been incorporated into the MMC as attachments; attachments may be considered by the Court on a motion to dismiss. E.g., Horsley v. Feldt, 304 F.3d 1125, 1134 (11th Cir. 2002) (noting that a court may consider a document attached to a complaint without converting the motion to dismiss into a motion for summary judgment if "the attached document is: (1) central to the plaintiff's claim; and is (2) undisputed"). The Court considers scientific studies about ranitidine and government publications about ranitidine to be central to the Plaintiffs' claims and to be undisputed documents. In the event the Plaintiffs disagree and instead believe that the cited documents and studies should not be considered by the Court, the Plaintiffs should omit the citations in any future pleading. At the Hearing, the Plaintiffs did not dispute that the Court could consider the cited documents, provided the content was not in dispute. Hearing Tr. at 209-10.

The studies divided NDMA consumption into quartiles, and the Court references those quartiles.

Suppose, for the sake of illustration, that the Plaintiffs allege that a typical Plaintiff consumes 50 ng of NDMA per day from food and water. Further suppose that the Plaintiffs rely upon the study at footnote 71 which found that there was a statistically significant increase in the rate of cancer for persons who consumed 510 ng per day. This would mean that, if the Plaintiffs allege that every ranitidine pill contained 360 ng (discussed below), then, according to the Plaintiffs' allegations the total daily NDMA consumption would be 50 + 360 = 410 ng. This number would fall short of the daily 510 ng cited in the study as showing a statistically significant increase in the rate of cancer.

The Court is also unable to apply the Plaintiffs' allegations to the NDMA studies of lifetime eating habits because the Court does not know the frequency of the Plaintiffs' ranitidine dosages (also discussed below). By way of example, if a typical Plaintiff consumed 50 ng of NDMA per day, and received 3,000 ng of NDMA from one ranitidine pill, but only consumed one pill per week, the Plaintiffs' weekly consumption of NDMA would still fall short of the daily 510 ng threshold discussed at footnote 71. In summary, the Court cannot ascertain from the MMC the amount of NDMA

the Plaintiffs contend would equate to a significant increase in the risk of cancer.

#### The Amount of NDMA in Each Ranitidine Dose

\*14 To the extent the Plaintiffs rely upon the 3,000 ng of NDMA per-dose referenced in their response, the Court has been unable to locate that number anywhere in the 2,192-page MMC, and the Plaintiffs provide no citation. Because the Plaintiffs argue in their response that the amount of NDMA per ranitidine pill is **over** 3,000 ng, the Court has conducted an extensive review of the MMC in an effort to determine the amount of NDMA each ranitidine dose is alleged to contain. The Court has been able to locate four different sets of numbers, and each set has been referenced by the Plaintiffs in their various responses throughout the entirety of this MDL; the Court addresses each set of numbers below.

First, the Court has been able to locate an allegation that each ranitidine dose contained 47,000 ng of NDMA. MMC ¶ 274. This number is sourced from a Stanford University study where researchers measured levels of NDMA in urine samples after a subject consumed a ranitidine pill. *Id.* The citation to the study is provided in footnote 126, however, when the Court utilized the citation to read the study, a red retraction notice appears on the top of the study:

### **Retracted article**

See the retraction notice

If the Plaintiffs' position is that the Court may conclude that the Plaintiffs have plausibly alleged a claim for medical monitoring based upon a retracted study, the Plaintiffs should clearly argue and explain that position. <sup>13</sup> In the absence of such argument, the Court does not conclude that a retracted study plausibly establishes a significantly increased risk of cancer.

According to the retraction notice, the study was retracted after the Plaintiffs filed the MMC.

The retraction notice indicates that the scientists'

measurements of NDMA were flawed and therefore unreliable.

Second, the Court has been able to locate an allegation that each ranitidine dose contained over 2,000,000 ng of NDMA. MMC ¶ 276. That number is sourced in the laboratory tests of a private company, Valisure. Id. Valisure arrived at that number by heating ranitidine to 266 degrees Fahrenheit. Id. Pursuant to the Plaintiffs' allegations, however, the temperature of the human body is 98.6 degrees, not 266 degrees. MMC ¶ 278. If the Plaintiffs' position is that the Court may conclude that the Plaintiffs have plausibly alleged a claim for medical monitoring based upon a study utilizing 266-degree temperatures, the Plaintiffs should clearly allege and explain that position. In the absence of such allegation, the Court does not conclude that a test utilizing 266 degrees of heat plausibly establishes a significantly increased risk of cancer, particularly given the additional findings of Valisure discussed below.

Valisure did not end its testing after the 266-degree test. Instead, Valisure conducted an additional test using 98.6 degrees of heat. MMC ¶ 281. That test detected no NDMA in ranitidine. *Id.* Valisure then conducted additional tests with a new variable.

Postulating that ranitidine degrades into NDMA when combined in the human stomach with foods rich in nitrites (such as tacos or pizza), Valisure conducted additional tests in an artificial human stomach where, using 98.6 degrees of heat, ranitidine was mixed with sodium nitrite. *Id.* Valisure's sodium nitrite findings are the third set of numbers that the Court has been able to locate in the MMC. Using "25 mM" of sodium nitrite in an artificial stomach, Valisure detected 23,600 ng of NDMA per ranitidine pill. *Id.* Using "50 mM" of sodium nitrite, Valisure detected 304,500 ng of NDMA per pill. *Id.* The Plaintiffs have repeatedly relied upon this 304,500 ng of NDMA number in their various filings in this Court. 14 Yet the amount of sodium nitrite necessary to produce this NDMA, 50 mM, is unaccompanied by explanation or context.

For example, on page 19 of the Plaintiffs' response, the Plaintiffs represent that the amount of NDMA found in one dose of ranitidine is as much as "3,100 times above the FDA-allowable limit." 3,100 x 96 = 297,600.

\*15 At the Court's initial conference on law and science, the Defendants gave their own opinion on what 50 mM of sodium nitrite means and whether such an allegation

renders the Plaintiffs' claims plausible. According to the Defendants, for a human stomach to contain the 50 mM of sodium nitrite necessary to produce 304,500 ng of NDMA, the consumer would first have to eat "33 pounds of bacon" before consuming ranitidine. DE 960 at 38. Because this statement was made to the Court outside of the briefing on the current Motion to Dismiss, the Court assigns no weight to the Defendants' position. The Plaintiffs did not offer their own explanation or context as to what 50 mM of sodium nitrite means, either in the MMC or in their response to the Motion to Dismiss. The Court gave the Plaintiffs the opportunity at the Hearing to explain the significance and context for 50 mM of sodium nitrite, but the Plaintiffs did not do so: "I don't have an opinion.... I would need to refresh my recollection from an expert." Hearing Tr. at 218.

In the absence of an explanation or context from the Plaintiffs, the Court endeavored to understand what, mathematically and scientifically, 50mM of sodium nitrite means. The Court attempted to perform its own mathematical calculations to discern the amount of bacon <sup>15</sup> necessary to collect 50 mM of sodium nitrite in the human stomach. The Court's own calculations estimated the amount of bacon to be necessary at around 25 pounds.

The reason the Defendants and the Court have utilized bacon as a baseline measurement is because bacon is particularly rich in sodium nitrite.

Just as the Court assigns no weight to the Defendants' representations about the significance of 50 mM, the Court similarly assigns no weight to its own calculations. The Court merely explains why the Plaintiffs must provide context and explanation if the Plaintiffs are to rely upon the 50mM number. Furthermore, the Plaintiffs' need to explain is directly traceable to the Plaintiffs' related allegations; Valisure concluded that 10 mM of sodium nitrite in the human stomach produced no NDMA. MMC ¶ 281. As a result, the difference between these two amounts of sodium nitrite matters pursuant to the Plaintiffs' own pleading-according to Valisure, 10 mM results in no NDMA, while 50 mM results in a large amount of NDMA. The Court therefore requires additional and sufficient allegations to determine that 50 mM represents an amount of sodium nitrite that plausibly supports a substantial increase in the risk of cancer, and 10 mM does not. If the Plaintiffs intend to rely upon either the 304,500 ng or 23,600 ng of NDMA found by Valisure, the Plaintiffs must clearly allege so in a manner that explains the significance and context of the amount of sodium nitrite utilized by Valisure,

together with the amount of food that would be necessary to generate that amount of sodium nitrite in the human stomach.

Fourth and finally, the Court has been able to locate allegations about the amount of NDMA in ranitidine from tests performed by the FDA. At footnote 90, the Plaintiffs incorporate a laboratory study by the FDA. In that study, the FDA tested a large number of ranitidine batches batches from many different manufacturers. Id. The amount of NDMA found in the ranitidine was not equal across the Manufacturing Defendants. <sup>16</sup> *Id.* For example, the NDMA found by the FDA ranged from 360 ng (Sanofi) to 4 ng (Pharma Associates). Id. One Defendant's ranitidine tested as having zero NDMA (Strides Shasun Ltd.). Id. Even if the Court were to utilize the highest amount of NDMA found by the FDA (360 ng) and assume that every Defendant's ranitidine had that much NDMA, that number is still an order of magnitude lower than the 3,000 ng number argued in the Plaintiffs' response.

The Court is uncertain whether it is the Plaintiffs' position that each Defendant's ranitidine was equally dangerous, given that the FDA found varying amounts of NDMA among the various Defendants' products.

The Court addresses one final point about the FDA's findings. In the FDA's own words, the "NDMA levels FDA found are similar to the levels a consumer would expect to be exposed to when eating common foods like grilled and smoked meats." MMC ¶ 237 n.87. For this reason, the FDA characterized the amount of NDMA in a ranitidine dose as "low levels." Id. The European Medicine Agency's findings (incorporated into the MMC) are similar: "Available safety data do not show that ranitidine increases the risk of cancer, and any possible risk is likely to be considered very low." MMC ¶ 249 n.102. If the Plaintiffs ultimately rely upon the FDA's findings to plausibly establish the amount of NDMA per ranitidine pill is around 360 ng, then the Plaintiffs should also explain why the statements of the FDA about the low levels of danger of ranitidine (also incorporated into the MMC) should be disregarded or otherwise not impact the Court's decision on plausibility.

\*16 In summary, with the possible exception of the FDA's findings, the Court is unclear on just how much NDMA exposure the Plaintiffs have alleged is caused through ranitidine ingestion. And, even if the Court were to base its plausibility determination on the FDA's findings, the Court is still unable to conclude that the Plaintiffs have plausibly alleged a significant increase in the risk of cancer because

of the Plaintiffs' lack of allegations about the *frequency* of ranitidine consumption, discussed below.

#### The Frequency of the Plaintiffs' Dosages

The Plaintiffs contend in their response that the MMC is specific about the number of doses that each Plaintiff received because each Plaintiff is alleged to have received "therapeutic dosages." On page 8 of the Plaintiffs' response, footnote 3, the Plaintiffs contend that "All MM Plaintiffs took therapeutic doses of ranitidine." For support, the Plaintiffs cite to paragraph 975 of the MMC. Paragraph 975 contains no information on the frequency of the Plaintiffs' dosages, only stating that the Plaintiffs "ingested [ranitidine] at various times as part of their treatment." That allegation says nothing about "therapeutic dosages." The Plaintiffs also cite to the individual Plaintiffs' allegations of dosage, but the Court has similarly been unable to locate the frequency of ranitidine use in those paragraphs. For example, the Plaintiffs cite to paragraph 93, but in that paragraph the Plaintiff only alleges that she used ranitidine products from 2009 to 2020. There is no allegation as to the frequency of use, nor is there a reference to "therapeutic dosages." The Plaintiffs' alleged class definitions similarly do not assist the Court, because the Plaintiffs define the class as being anyone "who used" ranitidine without qualification. E.g., MMC ¶ 993. The closest the Court can come to ascertaining a frequency of use is not in a specific paragraph in the MMC, but in the unnumbered introduction which states: "the typical recommended dose of ranitidine for therapy of peptic ulcer disease in adults is 150 mg twice daily or 300 mg once nightly for four to eight weeks, and maintenance doses of 150 mg once daily." If the Plaintiffs elect to allege that they took ranitidine according to this frequency, they should do so with clarity in the body of the MMC. Similarly, if the Plaintiffs allege that they took ranitidine with this frequency because they suffered from peptic ulcer disease, that too should be alleged with clarity. At present, the Court simply does not know the frequency with which the Plaintiffs have alleged they consumed ranitidine. Because the Court does not know the frequency, the Court does not know the amount of NDMA to which the Plaintiffs have alleged they were exposed. Without that information, the Court cannot ascertain whether the Plaintiffs have alleged they have a significantly increased risk of cancer.

The Level of Specificity Required in any Amended MMC

The Plaintiffs rely upon three cases to argue that they do not need to plead any additional facts in the MMC. First, the Plaintiffs cite to Trujillo v. Ametek, Inc., but in that case the plaintiffs were specific—the plaintiffs went so far as to allege with precision that their risk of cancer had increased from 5.6 chances in a million to 42 chances in a million. No. 15-CV-1394, 2015 WL 7313408, at \*6 (S.D. Cal. Nov. 18, 2015). Second, the Plaintiffs cite to *Allgood v. General Motors Corp.*, but in that case the trial court was not presented with a plausibility challenge on the "substantial increase" element; the trial court was even uncertain what, under Indiana law, the remedy of medical monitoring required. 2005 WL 2218371, at \*7-8. Third and finally, the Plaintiffs spent most of their argument at the Hearing and in their response in reliance upon In re Paulsboro Derailment Cases, and it is true that the *Paulsboro* court was presented with a plausibility challenge. No. 13-784, 2013 WL 5530050 (D.N.J. Oct. 4, 2013). It is equally true that the *Paulsboro* court was satisfied with the allegations in the complaint and required no further level of detail from the plaintiffs, however the Court sets forth below some of the allegations that the Court was able to locate in the *Paulsboro* complaint at docket entry 29 in the court file.

\*17 A train carrying vinyl chloride, a carcinogen, crashed, leaking the carcinogen into the water supply of a town and the air as well. Id. at p. 16. The leakage into the air created a poison mist, a fog. Id. The townspeople began to walk through the fog with small children, for example to get to school, and they were completely exposed. Id. The fog could be tasted in the mouths of those who walked through it. Id. at p. 17. Townspeople immediately received pain in their chests and eyes while inside the fog. Id. The pain lasted a long time. Id. Many townspeople developed debilitating coughs from walking through the fog, and the coughs lasted for several weeks. Id. Townspeople went to the hospital and were diagnosed as having been chemically exposed to a dangerous carcinogen. Id. The fog was sufficiently dangerous that townspeople were evacuated from their homes. Id. The Court is unpersuaded that this MDL is sufficiently analogous to Paulsboro such that the Court should not require an amended medical monitoring complaint. 17

In another area of the response, the Plaintiffs cite to *In re Valsartan, Losartan, & Irbesartan Products Liability Litigation*, MDL No. 2875, 2021 WL 364663, at \*4 (D.N.J. Feb. 3, 2021) and *Vavak v. Abbott Laboratories, Inc.*, No. SACV 10-1995, 2011 WL 10550065 (C.D. Cal. June 17, 2011), but neither of those cases considered

whether the Plaintiffs had plausibly alleged a significant increase in the risk of cancer.

In conclusion, the Court cannot clearly ascertain from the MMC: (i) the number of doses of ranitidine the Plaintiffs consumed, (ii) the amount of NDMA each Plaintiff received per dose, and (iii) how much NDMA is necessary to cause a significantly increased risk of cancer for each of the Subject Cancers alleged in the MMC. The Court does not mean to suggest that the only way that the Plaintiffs may plausibly plead a substantial increase in the risk of cancer is by answering in detail, through their allegations, the questions the Court has posed or by dispelling all of the uncertainty that the Court has highlighted in this Order. The Plaintiffs may, of course, plead a substantial increase in the risk of cancer in whatever way they deem best, including through avenues other than NDMA exposure and NDMA frequency. The Court's ruling is merely that, as pled, the Court cannot conclude that the Plaintiffs have plausibly alleged a substantial increase in the risk of cancer. The Plaintiffs must replead their medical monitoring claims, and the MMC is dismissed without prejudice and with leave to amend.

<u>Diagnostic Testing</u>: The Defendants argue that the Plaintiffs have not plausibly pled that testing exists to detect their alleged cancers early. DE 3116 at 24. The Plaintiffs respond that they satisfy this element by alleging that the required monitoring would include "baseline tests and periodic diagnostic examinations that will assist in early detection and diagnosing the Subject Cancers." DE 3429 at 26.

The Court concludes that the Plaintiffs have failed to plausibly allege that diagnostic tests exist for early detection of the Subject Cancers. The Plaintiffs' allegation amounts to a "naked assertion devoid of further factual enhancement." *Iqbal*, 556 U.S. at 678, 129 S.Ct. 1937. The Plaintiffs do not expressly allege that any tests and exams *exist*, much less specify what they are.

The Defendants' caselaw is persuasive. In *Slemmer v. McGlaughlin Spray Form Insulation, Inc.*, the plaintiffs proposed a monitoring regime of "diagnostic tests and pharmaceutical interventions." No. 12-6542, 2013 WL 5655480, at \*3 (E.D. Pa. Oct. 17, 2013). Their class action complaint was dismissed for "fail[ure] to identify specific medical monitoring procedures as required," and for "fail[ure] to aver that a monitoring program procedure exists that makes early detection of a specific disease possible." *Id.*; see also In re Avandia Mktg., Sales Practices & Prods. Liab. Litig., MDL Nos. 1871, 07-MD-01871, 2011 WL 4006639,

at \*3 (E.D. Pa. Sept. 7, 2011) (granting a motion to dismiss where "[t]he claim for medical monitoring essentially tracks the elements of the claim, but without any specific facts alleged (e.g., as to what medical monitoring procedure exists and how it differs from the monitoring for all patients with Type 2 diabetes)"). Additionally, the Defendants cite *Bell v*. 3M Co., where medical monitoring claims were dismissed for, among other deficiencies, the plaintiffs' failure to allege that there were any diagnostic tests that could detect the plaintiffs' diseases early. 344 F. Supp. 3d 1207, 1227 (D. Colo. 2018). At the Hearing, counsel for the Defendants noted that, in Bell, the plaintiffs subsequently filed an amended complaint alleging sufficient factual detail regarding the tests and evaluations that were needed. Hearing Tr. at 208. The Court's review of the relevant pleading in Bell confirms this point. See Third Am. Class Compl. with Individual Claims and Demand for Jury Trial, Bell v. 3M Co., No. 16-cv-02351-RBJ (D. Colo. Oct. 5, 2018), CM/ECF No. 333, ¶¶ 140-42, 224.

\*18 Courts overseeing large cases—including those involving medical monitoring claims—have demanded specificity in pleadings before permitting the case to advance further. See, e.g., Cook v. Rockwell Intern. Corp., 755 F. Supp. 1468, 1475 (D. Colo. 1991) ("In a case of this magnitude, a district court must retain the power to insist upon some specificity in pleading before allowing a potentially massive factual controversy to proceed.") (quotation marks omitted). As to this element, the Plaintiffs' current allegations lack the specificity present in the Third Amended Complaint in *Bell.* They likewise suffer from deficiencies similar to those in the complaints that were dismissed in *Slemmer*, *Avandia*, and Bell. The Court will not permit those deficiencies, and thus dismisses the Plaintiffs' medical monitoring claims in all jurisdictions requiring a diagnostic testing element. 18 At the Hearing, counsel for the Plaintiffs stated that on replead, the Plaintiffs could provide greater specificity as to this element:

[The Court:] If the Court finds the Defendants' argument is persuasive, and if you were to replead ... could you allege on a replead that diagnostic testing exists to make early detection of the [S]ubject [C]ancers possible? ....

Ms. Meeder: Your Honor, I understand you to be asking if we could plead the specific tests, because we do plead generally that there are baseline and other diagnostic tests that exist. I am understanding we are talking about specific tests.

If your Honor would like us to replead this with more specificity, we are able to do so.

Hearing Tr. at 198-99. The Plaintiffs' claims are thus dismissed without prejudice on this basis, and with leave to replead as to this specific element.

In their Motion to Dismiss, the Defendants included a footnote citing those jurisdictions which they believe require this element. DE 3116 at 24 n.6. The Plaintiffs did not respond to the footnote. In any repleading, it is incumbent upon the Plaintiffs to ascertain what each jurisdiction requires and amend the MMC accordingly, consistent with the Court's ruling.

Medical Monitoring Regime: The Defendants argue that the Plaintiffs have not pled that their proposed monitoring regime differs from what is normally recommended absent exposure. DE 3116 at 26. The Plaintiffs argue that they plausibly plead this element by alleging that "[t]he latent injuries from which Plaintiffs [and] the Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large," and that the regime "is different from that normally recommended in the absence of exposure to this risk of harm." DE 3429 at 26 (citing MMC ¶ 979).

The Court concludes that the Plaintiffs' allegations are merely a recitation of the required element. Indeed, the Plaintiffs' allegations are like those in cases that Defendants cite, where medical monitoring claims were dismissed. See Coffie v. Fla. Crystals Corp., 460 F. Supp. 3d 1297, 1314 (S.D. Fla. 2020) (dismissing a medical monitoring count where plaintiffs "merely pled a formulaic recitation of" the required elements, including that the regime differed from what is normally recommended absent exposure, and did not provide supporting facts); Barker v. Naik, No. 2:17-cv-04387, 2018 WL 3824376, at \*5 (S.D. W. Va. Aug. 10, 2018) (dismissing a medical monitoring claim where plaintiffs' allegations mirrored the necessary factors-including that they needed to "undergo periodic diagnostic medical examinations different from what would be prescribed in the absence of their exposure"—but failed to allege supporting facts); Gibson v. Lapolla Indus., Inc., No. 6:13-cv-646-Orl-36KRS, 2014 WL 12617007, at \*4 (M.D. Fla. Jan. 31, 2014) (dismissing a medical monitoring claim where plaintiff pled "a rote recitation of the required elements," including that "[m]onitoring procedures exist that make the early detection of any latent disease possible that are different from those normally recommended in the absence of the exposure").

\*19 Although Rule 8 does not require that a pleading contain an extraordinary level of detail, the Court will not accept a

pleading that merely recites a necessary element and does not provide any factual support. The Court thus dismisses the Plaintiffs' medical monitoring claims in all jurisdictions requiring that a proposed monitoring regime differ from what is recommended to the public at large. At the Hearing, counsel for the Plaintiffs stated that they may be able to allege more regarding this element. Hearing Tr. at 203 ("[T]here may be a bit measure more of explanation that we could plead ...."). The Plaintiffs' claims are therefore dismissed without prejudice, and with leave to replead as to this specific element.

### 3. Failure to Plead the Claims Based on Expiration Dates and Product Containers

#### a. Arguments and Allegations

The Defendants contend that the Plaintiffs have failed to plausibly plead the claims based on improper expiration dates and product containers, and the Defendants therefore seek dismissal of all of these claims in the MMC. 19 DE 3116 at 27-29. The Plaintiffs have not plausibly alleged that any Defendant knew or should have known that ranitidine degrades to form NDMA over time or due to exposure to moisture. Id. The Plaintiffs respond that they have plausibly alleged that the Defendants knew or should have known that ranitidine degrades into NDMA due to time and exposure to moisture because (i) the ranitidine molecule contains all of the ingredients needed to form NDMA, (ii) federal law requires drug manufacturers to conduct stability testing on their products to assess drug stability, and (iii) research published in the 1980's revealed elevated levels of NDMA in ranitidine. DE 3429 at 31-34.

The Defendants do not make this argument as to the claims for negligent storage and transportation.

The Plaintiffs allege that ranitidine internally degrades to form NDMA, that the level of NDMA in a ranitidine product increases over time, and that this higher level of NDMA increases the risk of cancer. See, e.g., MMC ¶¶ 880-81, 883. The cancer risk is lower if the product is consumed shortly after it is manufactured. Id. ¶¶ 882-83. Therefore, had ranitidine products had shorter expiration dates, the ranitidine that consumers ingested would have had lower levels of NDMA, and their cancer risks would have been lower. Id. ¶ 883. Pill bottles with a large number of pills are likely to be stored for long periods of time. Id. ¶ 941. Selling ranitidine products with a smaller quantity of pills in each bottle would have ensured that the products were fully consumed closer

to their dates of manufacture, when they contained lower levels of NDMA. *Id.* ¶ 942. Ranitidine internally degrades to form NDMA more quickly at higher humidity levels. *Id.* ¶ 938. Packaging ranitidine pills "in a blister pack or similar individually packaged container" would have protected them from exposure to humidity. *Id.* ¶ 942.

The Plaintiffs also allege that the Defendants knew or should have known about all of the risks associated with ranitidine. Id. ¶ 183. They "knew or should have known that ranitidine had an inherent risk of degrading into NDMA because it has both a nitroso (N) and dimethylamine (DMA), which are all the ingredients needed to form NDMA." Id. ¶ 939. Federal law requires drug manufacturers to conduct stability testing on their products to assess drug stability and to determine appropriate storage conditions and expiration dates. Id. ¶¶ 885-86; see 21 C.F.R. § 211.166(a) ("There shall be a written testing program designed to assess the stability characteristics of drug products. The results of such stability testing shall be used in determining appropriate storage conditions and expiration dates."). "Simple, widely available and cost-effective tests" would have reveled degradation and NDMA accumulation in ranitidine products. MMC ¶ 882-84. Furthermore, research conducted and published before Zantac entered the market revealed elevated levels of NDMA in ranitidine when it was properly tested. *Id.* ¶ 312. For example, a doctor published a note in a popular scientific journal in 1981 that discussed "the results of his experiments showing that ranitidine was turning into mutagenic N-nitroso compounds, of which NDMA is one, in human gastric fluid when accompanied by nitrites—a substance commonly found in food and in the body." *Id.* ¶ 314.

#### b. Analysis and Conclusion

\*20 The parties utilize a "known or should have known" standard in making their respective arguments about the sufficiency of the pleading. The parties have not briefed whether any state's law would use a different standard to meet the element of notice for any of the claims at issue. For purposes of analyzing the adequacy of the Plaintiffs' pleading, the Court utilizes a "known or should have known" standard. Should any party contend that the standard is different under a particular state's law, that party may raise the issue at the appropriate time in connection with state-specific arguments. See Pretrial Order # 61 ("To the extent that other state-specific issues become relevant at a later stage of the litigation, such as at the bellwether trial stage, the parties agree

that they may seek leave of the Court to raise the issues at that time.").

The Plaintiffs have plausibly pled that the Defendants should have known, through stability testing of their ranitidine products, that ranitidine can degrade to form NDMA over time and due to exposure to moisture. The Plaintiffs allege that federal law requires all drug manufacturers to conduct stability testing on their products to assess drug stability and to determine appropriate storage conditions and expiration dates. MMC ¶ 886 (citing 21 C.F.R. § 211.166). The Plaintiffs further allege that testing would have revealed degradation and NDMA accumulation in ranitidine products. *Id.* ¶ 884.

The Defendants argue that the Plaintiffs' allegations about stability testing are insufficient because they do not identify which tests the Defendants should have conducted that would have revealed ranitidine degradation or when such tests became available. DE 3116 at 28. The Defendants assert that some of them manufactured ranitidine products decades in the past. *Id.* 

But the Plaintiffs have identified one test that they maintain could have detected NDMA and that was available at all times that ranitidine products were manufactured. That is, the Plaintiffs have alleged that "mass spectrometry" was a "goldstandard" test that was available by at least 1982, around the same time that the FDA approved the first ranitidine product for sale. MMC ¶ 264 (faulting a 1982 GSK study for failure to use "gold-standard mass spectrometry"), ¶ 151 (alleging that the FDA approved the sale of Zantac in 1983). And the Plaintiffs have alleged that "gas chromatography-mass spectrometry" testing in 2019 revealed high levels of NDMA in ranitidine pills. Id. ¶ 230. These allegations, in conjunction with the allegations about federal requirements for stability testing and the availability of testing that would have revealed degradation, plausibly plead that the Defendants should have known that ranitidine can degrade to form NDMA with time and with exposure to moisture. 20 Therefore, the Plaintiffs have plausibly pled notice for the claims based on expiration dates and product containers. The Defendants' request to dismiss those claims is denied.

Given this conclusion, the Court does not address the parties' arguments about notice based on ranitidine's molecular structure and research from the 1980s.

## 4. Viability and Pleading of the Claims for Failure to Warn Consumers Through the FDA

The Plaintiffs bring claims against the Manufacturer Defendants in the MMC for failure to warn consumers through the FDA. These claims are raised under the laws of California, the District of Columbia, Indiana, Maryland, Missouri, Nevada, and Pennsylvania. The Plaintiffs allege that the Manufacturer Defendants breached their duties, under the laws of these jurisdictions, to convey warnings to the FDA of the dangers of ranitidine products when those warnings could have reached consumers. *See, e.g.*, MMC ¶ 1068-69.

The Manufacturer Defendants argue that the claims must be dismissed because they are not viable under the laws of the seven jurisdictions and because the claims are not plausibly pled. DE 3116 at 29-33. The Plaintiffs' response incorporates by reference their opposition to the dismissal of Count V of the AMPIC, another claim for failure to warn consumers through the FDA. DE 3429 at 34; see DE 3424. The Plaintiffs argue that their claims are plausibly pled and that the Manufacturer Defendants incorrectly interpret state law in reaching their conclusion that jurisdictions would not recognize the claims. DE 3424 at 35-44. The Plaintiffs concede that the District of Columbia and Indiana would not recognize the claims, and they seek leave to amend their pleading to raise the claims under the laws of Idaho and Wisconsin. *Id.* at 45.

\*21 In the Court's Order Granting in Part and Denying in Part the Branded Defendants' Rule 12 Partial Motion to Dismiss Plaintiffs' Three Master Complaints as Preempted by Federal Law, the Court concluded that the Plaintiffs' claims for failure to warn consumers through the FDA are preempted under *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001), for the reasons that the Eleventh Circuit Court of Appeals outlined in *Mink v. Smith & Nephew, Inc.*, 860 F.3d 1319, 1330 (11th Cir. 2017). The Court dismisses the claims with prejudice for that reason. In light of this ruling, the Court need not address arguments directed to the viability of the claims under state law and pleading deficiencies or the Plaintiffs' request to add sub-counts under the laws of Idaho and Wisconsin.

#### 5. Claim Splitting

The Defendants argue that the Plaintiff's have impermissibly split their claims between the MMC and the ELC. This is impermissible, the Defendants argue, because in the Eleventh Circuit all of a plaintiff's related claims must be brought in one pleading. As explained by the Eleventh Circuit: "The rule against claim-splitting requires a plaintiff to assert all of its causes of action arising from a common set of facts in one

lawsuit." *Vanover v. NCO Fin. Servs., Inc.*, 857 F.3d 833, 841 (11th Cir. 2017). The rule exists "to allow district courts to manage their docket and dispense with duplicative litigation." *Id.* The Defendants' claim-splitting argument is premature for several reasons.

First, there is no "duplicative litigation," because there is but one case pending before the Court—this MDL—and all other cases have been administratively closed pending remand. Second, the reason the Plaintiffs have arguably split their claims between two master pleadings is because the Court expressly granted the Plaintiffs permission to do so at docket entry 2720. Third, the reason the Court granted the Plaintiffs permission to file an additional master complaint was because the Court was exercising its authority to "manage [its] docket."<sup>21</sup> The Court will not penalize the Plaintiffs through dismissal for filing a master pleading that the Court expressly authorized. Fourth and finally, once the pleadings have closed and this matter is ripe for remand the Defendants may, upon proper motion, raise this issue anew. The Defendants may raise this issue at such time to the extent they believe it is necessary to avoid duplicative litigation in any transferee court. At this stage of the MDL, the Court denies without prejudice the Defendants' request to dismiss any complaint because of improper claim splitting.

Furthermore, the reason an additional master pleading is useful to the Court is because it assists the Court in analyzing *the Defendants*' motion to dismiss challenges. See generally DE 2515.

#### 6. Factual Inconsistencies

The Defendants argue that certain counts in the class complaints are factually inconsistent because, within the allegations incorporated into the counts, the Plaintiffs advance multiple theories as to how ranitidine injured the Plaintiffs. *E.g.*, MMC ¶¶ 185-304. The Defendants contend that these different theories of injury are inconsistent. In response, the Plaintiffs argue that their theories are not inconsistent—they simply postulate *different* explanations for the Plaintiffs' injuries, not *inconsistent* explanations. The Court concludes that Plaintiffs' claims need not be dismissed or amended based on these alleged inconsistencies. To the extent the Plaintiffs' various theories for recovery implicate pre-emption concerns, that is a matter that will be addressed in the Court's Order on the Generic Defendants' Rule 12 Motion to Dismiss on the Ground of Preemption.

#### B. Issues Raised in the ELC

#### 1. Shotgun Pleading

#### a. Arguments and Allegations

\*22 The Defendants argue that the ELC is still a shotgun pleading that violates Rule 8, despite the Court's Order at docket entry 2515 ("Shotgun Order") noting that the ELC impermissibly incorporated hundreds of allegations into every count and lumped the Defendants together. DE 3116 at 35. Rather than cure those deficiencies, the Plaintiffs merely re-organized their claims. Id. In turn, each of the ELC's 1,675 counts still incorporate hundreds of paragraphs of allegations, and many of the same paragraphs are alleged against all the Defendants. Id. at 36. While all the Defendants are no longer lumped together in the same counts, the Plaintiffs still sue multiple Defendants for identical claims without differentiating their actions. Id. As to their fraud-based claims that are subject to Rule 9(b), the Plaintiffs' pleading falls even shorter. Id. at 38. The Plaintiffs' shotgun pleading again precludes the Court from undertaking a proper standing analysis. Id. at 37.

The Plaintiffs argue that the ELC neither impermissibly incorporates paragraphs nor lumps the Defendants together. DE 3429 at 40-41. The Plaintiffs incorporate only relevant factual allegations into each count, and it is of no consequence that there may be hundreds of relevant paragraphs. *Id.* at 40. The Plaintiffs also separately set forth each Defendant and each claim in the ELC. *Id.* at 41.

#### b. Law on Shotgun Pleading

Rule 8(a) requires that any claim for relief contain "a short and plain statement of the claim showing that the pleader is entitled to relief." Fed. R. Civ. P. 8(a)(2). A shotgun pleading fails "to one degree or another, and in one way or another, to give the defendants adequate notice of the claims against them and the grounds upon which each claims rests." *Weiland v. Palm Beach Cnty. Sheriff's Office*, 792 F.3d 1313, 1323 (11th Cir. 2015). There are roughly four types of shotgun pleadings:

The most common type—by a long shot—is a complaint containing multiple counts where each count adopts the allegations of all preceding counts, causing each successive count to carry all that came before and the last count to be a combination of the entire complaint. The next most

common type ... is a complaint that does not commit the mortal sin of re-alleging all preceding counts but is guilty of the venial sin of being replete with conclusory, vague, and immaterial facts not obviously connected to any particular cause of action. The third type of shotgun pleading is one that commits the sin of not separating into a different count each cause of action or claim for relief. Fourth, and finally, there is the relatively rare sin of asserting multiple claims against multiple defendants without specifying which of the defendants are responsible for which acts or omissions, or which of the defendants the claim is brought against.

*Id.* at 1321-23 (footnotes omitted).

Rule 9(b) states that "[i]n alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake." Fed. R. Civ. P. 9(b). To satisfy Rule 9(b), a complaint must set forth:

(1) precisely what statements were made in what documents or oral representations or what omissions were made, and (2) the time and place of each such statement and the person responsible for making (or, in the case of omissions, not making) same, and (3) the content of such statements and the manner in which they misled the plaintiff, and (4) what the defendants obtained as a consequence of the fraud.

*Ziemba v. Cascade Int'l, Inc.*, 256 F.3d 1194, 1202 (11th Cir. 2001).

#### c. Analysis and Conclusion

In the Shotgun Order, the Court concluded that the Plaintiffs (1) impermissibly incorporated hundreds of allegations into every count, and (2) impermissibly lumped related and unrelated Defendants together. DE 2515 at 22. The Defendants argue that the ELC still commits both sins. The Court disagrees.

As noted in the Shotgun Order, the original ELC indiscriminately incorporated the first 748 paragraphs into all 314 counts, including every factual allegation. *Id.* Such wholesale incorporation is not present in the amended ELC, as each count incorporates a narrower set of allegations. *See, e.g.,* ELC ¶¶ 1302, 1304. Although the Defendants argue that many of the same voluminous allegations are alleged against each Defendant, that does not, by necessity, deprive the Defendants of notice of the claims against them. *Cf. Kyle K. v. Chapman*, 208 F.3d 940, 944 (11th Cir. 2000) (complaint

not a shotgun pleading) ("[T]he complaint can be fairly read to aver that all defendants are responsible for the alleged conduct."); *Bailey v. Janssen Pharmaceutica, Inc.*, 288 F. App'x 597, 603 (11th Cir. 2008) ("[A] complaint—so long as it is minimally sufficient to put a defendant on notice of the claims against him—will not fail for mere surplusage."); *In re Trasylol Prods. Liab. Litig.*, No. 08-MD-1928, 2009 WL 577726, at \*6 (S.D. Fla. Mar. 5, 2009) (citing *Bailey* and concluding that MDL master complaint was not a shotgun pleading).

\*23 Separately, the Defendants argue that the Plaintiffs "still lump groups of Defendants together and allege in undifferentiated fashion the purported conduct supposedly underlying the subsequent, separated claims." DE 3508 at 19. Contrary to the Defendants' argument, the Plaintiffs appear to have eliminated the lumping that the Court found problematic in the original ELC. While many counts in the original ELC were alleged against multiple groups of Defendants, or all Defendants, each count in the amended ELC appears to be alleged against one specific Defendant (or related Defendants). Compare DE 889 at 354 (Count 9, violation of the Alabama Deceptive Trade Practices Act, alleged "Against Brand-Name Manufacturer Defendants and Generic Manufacturer Defendants"), with ELC at 1554 (Count 409, violation of the Alabama Deceptive Trade Practices Act, alleged "Against Amneal").

Finally, the Defendants' argument that the Plaintiffs' "fraud-based claims" fail under Rule 9(b) is unpersuasive. DE 3116 at 38. The Defendants appear to devote just one sentence in their Motion to this argument, and do not specify which of Plaintiffs' ELC counts are "fraud-based claims." Absent adequate briefing on the issue, the Court declines to consider the matter.

Even if the Defendants view the ELC as imperfect, the Court is satisfied that the Plaintiffs have adequately addressed the shotgun pleading sins that were previously present. The ELC need not be perfect; it need only provide the Defendants with fair notice of the allegations. *Twombly*, 550 U.S. at 554-56. If the Court ordered the Plaintiffs to replead with the detail that the Defendants demand, the ELC would likely balloon to thousands of more pages and make an already massive pleading even larger. That would in turn jeopardize one major purpose of multidistrict litigation, namely to "promote the *just and efficient conduct*" of "actions involving one or more common questions of fact pending in different districts." 28 U.S.C. § 1407(a) (emphasis added).

Particularly in an MDL of this size, a district court retains wide discretion to ensure that the litigation progresses efficiently and without undue delay. This Court has exercised that discretion at various stages of the litigation in order to efficiently administer this MDL, including through the issuance of more than 60 Pretrial Orders. Its conclusion on this issue is consistent with fulfilling the Court's obligation to properly manage the MDL.

#### 2. Article III Standing: Injury-in-Fact

#### a. Arguments and Allegations

Renewing an argument raised in a prior motion to dismiss, <sup>22</sup> the Defendants argue that the ELC should be dismissed because the Plaintiffs fail to plead an injury-in-fact to satisfy Article III standing. DE 3116 at 38. The Defendants argue that in an earlier Order, the Court rejected the Plaintiffs' theory of economic injury based on *Debernardis v. IQ Formulations*, LLC, 942 F.3d 1076 (11th Cir. 2019). Id. at 38-39 (discussing DE 2515). On replead, "Plaintiffs' burden [was] to supply plausible factual allegations explaining their assertions of economic loss for a ranitidine medication created 'exactly in the manner in which the FDA approved it." "Id. at 39 (citing DE 2515 at 43). Yet the Plaintiffs rely on "the same rejected theory that all ranitidine-containing medications are defective as approved, and therefore 'worthless' or 'worth less' because the Plaintiffs would not have made their purchases if they had known of the purported 'safety risks.' " DE 3508 at 19-20 (citing DE 3429 at 18-22). The Plaintiffs do so without any new supporting factual allegations, and in lieu of attributing their losses to the conduct that is now allegedly at issue, namely expiration dates, packaging, and storage. But the Plaintiffs' allegations again fall short under *Debernardis* and do not constitute a concrete, particularized, and actual or imminent harm that is required for Article III standing. DE 3116 at 39; DE 3508 at 20. The Plaintiffs do not allege that the ranitidine they took was ineffective, and although they allege that NDMA is a carcinogen with dangerous properties. the Plaintiffs do not allege that they experienced toxic or carcinogenic consequences due to ingesting the Defendants' ranitidine products. Id. Absent allegations of physical injury or inefficacy, the Plaintiffs cannot allege that they purchased a "worthless" product. Id.

22 See DE 2037.

\*24 The Plaintiffs respond that they plausibly plead an economic injury, since they purchased ranitidine products that they would not have bought had they known that the products cause cancer. DE 3429 at 35. Their financial injury is equal to the price that they paid for the products, which is adequate for Article III standing. *Id.* at 36. The Plaintiffs' case is exactly like *In re Valsartan, Losartan, & Irbesartan Products Liability Litigation*, MDL No. 2875, 2021 WL 100204 (D.N.J. Jan. 12, 2021). *Valsartan* also involved allegations that the defendants' products contained NDMA, and the district court found that the plaintiffs pled an injury-in-fact by alleging that they did not receive the benefit of their bargain when purchasing the defendants' products. *Id.* at 37.

While the Plaintiffs do not rely exclusively on *Debernardis* to establish injury-in-fact, the case's principles apply here. including that under a benefit-of-the-bargain theory, a purchaser who buys a product with significant defects may receive nothing of value. Id. The Plaintiffs' case is stronger than Debernardis, for the Plaintiffs here allege a substantive safety defect—that the Defendants' products contained NDMA—while the plaintiffs in Debernardis alleged a procedural defect, namely that the defendants sold a presumptively adulterated dietary supplement containing an ingredient that the FDA had not approved. Id. at 37-38. In this regard, the Plaintiffs' case is more like *In re Aqua* Dots Products Liability Litigation, 654 F.3d 748 (7th Cir. 2011), wherein the plaintiffs alleged that they would not have purchased the defendants' products had they known of their real-world defects. Id. at 38. Further, the Defendants' argument that the Plaintiffs allege neither physical injury, nor that the ranitidine products were ineffective, is unpersuasive, as the Plaintiffs' theory of economic injury is not premised on those circumstances, and courts have routinely rejected the Defendants' argument. Id. at 38-39. Finally, that the FDA approved the Defendants' products does not impact the Plaintiffs' injury, since the Plaintiffs allege that the products contain NDMA and cause cancer, and they would not have purchased ranitidine products had they known. Id. at 39.

#### b. Law on Article III Injury-In-Fact

"Article III, § 2, of the Constitution extends the 'judicial Power' of the United States only to 'Cases' and 'Controversies.' " *Steel Co. v. Citizens for a Better Env't*, 523 U.S. 83, 102 (1998). That a case or controversy exists is a bedrock requirement, and courts cannot exercise judicial power without it. *Muransky v. Godiva Chocolatier, Inc.*, 979

F.3d 917, 924 (11th Cir. 2020) (en banc). "Standing, ripeness and mootness are three traditional doctrines governing whether a case or controversy exists." *Id.* Standing is "perhaps the most important of the jurisdictional doctrines." *Id.* (quotation marks omitted).

The "irreducible constitutional minimum of standing" entails three elements: injury-in-fact, causation, and redressability. *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560-61, 112 S.Ct. 2130, 119 L.Ed.2d 351 (1992). The party invoking federal jurisdiction bears the burden of establishing each element. *Id.* at 561, 112 S.Ct. 2130. The *Lujan* elements are "an indispensable part of the plaintiff's case, [and] each element must be supported in the same way as any other matter on which the plaintiff bears the burden of proof, *i.e.*, with the manner and degree of evidence required at the successive stages of the litigation." *Id.* 

The Defendants only challenge the injury-in-fact element. To show an injury-in-fact, a plaintiff must demonstrate "an invasion of a legally protected interest" that is "concrete and particularized" and "actual or imminent, not conjectural or hypothetical." *Id.* at 560, 112 S.Ct. 2130 (quotation marks omitted). A particularized injury is one that "affect[s] the plaintiff in a personal and individual way." *Spokeo, Inc. v. Robins*, 136 S. Ct. 1540, 1548 (2016). A concrete injury is one that is "real" and not "abstract." *Id.* A plaintiff can allege concrete harm in three ways:

\*25 First, he can allege a tangible harm—a category that is the most obvious and easiest to understand and that includes, among other things, physical injury, financial loss, and emotional distress. Second, a plaintiff can allege a risk of real harm. Third, in the absence of a tangible injury or a risk of real harm, a plaintiff can identify a statutory violation that gives rise to an intangible-but-nonetheless-concrete injury.

Hunstein v. Preferred Collection and Mgmt. Servs., Inc., 994 F.3d 1341, 1346 (11th Cir. 2021) (quotation marks and citations omitted).

"At the pleading stage, general factual allegations of injury resulting from the defendant's conduct may suffice, for on a motion to dismiss we presume that general allegations embrace those specific facts that are necessary to support a claim." *Lujan*, 504 U.S. at 561, 112 S.Ct. 2130. "But that is not a free pass—these general factual allegations must plausibly and clearly allege a concrete injury," and mere conclusory allegations are insufficient. *Godiva*, 979 F.3d at 924 (quotation marks omitted). Courts "will not imagine or

piece together an injury sufficient to give a plaintiff standing when it has demonstrated none," and "are powerless to create jurisdiction by embellishing a deficient allegation of injury." *Id.* at 925 (quotation marks omitted).

Economic harm is the epitome of a concrete injury. MSPA Claims 1, LLC v. Tenet Fla., Inc., 918 F.3d 1312, 1318 (11th Cir. 2019). A person experiences economic harm when, due to a defendant's conduct, she is deprived of the benefit of her bargain. Debernardis, 942 F.3d at 1084. Under a benefit-of-the-bargain theory, damages are generally equal to the difference in value between the product in the condition in which it was delivered versus its value if it were delivered in the condition according to the parties' contract. Id. "Ordinarily, when a plaintiff purchases a product with a defect, the product retains some value, meaning her benefitof-the-bargain damages are less than the entire purchase price of the product." *Id.* Yet when a product is rendered valueless due to a defect, a plaintiff receives a worthless product, and his or her damages are equal to the product's full purchase price. Id. "The benefit-of-the-bargain theory thus recognizes that a purchaser who acquires a product with significant defects may effectively receive nothing of value." Id.

#### c. Analysis and Conclusion

Relying on a benefit-of-the-bargain theory, the Plaintiffs allege that they have suffered tangible harm through financial loss. E.g., ELC ¶¶ 92-272 (The Plaintiffs have "suffered concrete injury in the form of economic damages," since due to the Defendants' conduct, the ranitidine products they purchased "were unsafe for human ingestion and, therefore, were worthless at the time of purchase"); id. ¶ 1319 ("Had Defendant not engaged in the deceptive acts and practices alleged herein, Plaintiff and the Class members would not have purchased the drug, and, thus, they did not receive the benefit of the bargain and/or suffered out-ofpocket loss."). The Plaintiffs' theory for injury-in-fact is not premised on present physical injury, an increased risk of some future injury, or "statutory violation that gives rise to an intangible-but-nonetheless-concrete injury." Hunstein, 994 F.3d at 1346.<sup>23</sup>

This is so despite permission from the Court for the Plaintiffs to seek leave to allege class physical injuries through an alternative class pleading. The Court stated that the Plaintiffs, "without any prejudice to their substantive claims, may seek leave of Court for

an alternative pleading to allege their *class physical injury and/or medical monitoring claims*." *Id.* (emphasis added). During the December 14, 2020 hearing, the Plaintiffs suggested that moving their allegations of physical injury to another pleading would not be problematic. DE 2498 at 161-62.

The Plaintiffs subsequently moved to certify a question for interlocutory appeal. DE 2693. In that motion, the Plaintiffs argued that because of the Court's Order on preemption for Brand-Name Manufacturer Defendants [DE 2532], they could no longer allege economic loss claims premised on personal injury. The Court denied the motion without prejudice, and re-clarified that its prior Order did not preclude the Plaintiffs from pleading as they described. DE 2716 at 2. The Plaintiffs' decision to premise their economic loss purely on purchasing an allegedly unsafe and worthless product—rather than on personal injuries—was not because they were prohibited from doing so. At the Hearing, the Plaintiffs confirmed that they were aware of their right to seek leave to file a class personal/physical injury complaint, but did not exercise it. Hearing Tr. at 167-68.

\*26 The Court concludes that at this procedural juncture, the Plaintiffs have plausibly alleged economic injury-in-fact through purchasing worthless drugs that contained NDMA and were misbranded, and which the Plaintiffs would not have purchased but for the Defendants' conduct. This conclusion is supported by allegations throughout the ELC, including those discussed below.

The Plaintiffs allege that NDMA has been a known human carcinogen since the 1970s. ELC ¶ 443. Two years before Zantac entered the market, Dr. Silvio de Flora published research warning of "toxic and mutagenic effects" when ranitidine interacted with human gastric fluid and nitrites. Id. ¶¶ 373, 388. Dr. de Flora's research was allegedly "known to GSK and should have been known by each Defendant prior to their manufacturing, marketing, labeling, packaging, handling, distribution, and/or sale of ranitidine as the information was available in medical literature." *Id.* ¶ 445. Yet GSK attempted to discredit Dr. de Flora's research, and the Defendants could and should have known of those attempts. Id. ¶ 447. Furthermore, at various times, GSK conducted studies investigating the relationship between ranitidine and NDMA, some of which were flawed. E.g., id. ¶¶ 395, 446, 448, 450, 452. "Defendants either knew or should have known about the inadequacy of GSK's studies, the impact and cautionary instructions of independent studies, and should have, through due diligence and/or their own independent testing, investigated the issue properly and/or took action to protect consumers from the NDMA risks in their products." *Id.* ¶ 454.

The Plaintiffs later allege that pursuant to federal regulations, the Defendants were required to inform the FDA annually about new information affecting ranitidine's safety, effectiveness, or labeling. Id. ¶¶ 464-65. Despite publicly available science demonstrating that ranitidine products contained and exposed users to NDMA, the Defendants allegedly disregarded that science and never disclosed those risks to the FDA, in violation of their reporting obligations. Id. ¶¶ 462, 466-68. "Because Manufacturer Defendants never properly disclosed the risks to the FDA, they never proposed any labeling or storage / transportation guidelines that would have addressed this risk." Id. ¶ 468. Yet once the FDA learned about the NDMA risks associated with ranitidine products, it ordered voluntary recalls of the products. Id. ¶¶ 372, 469. Had any Manufacturer Defendant notified the FDA about the risks sooner, the FDA would have ordered the ranitidine products removed from the market. Id. ¶ 469. And by failing to include warnings on labels that consumers were at elevated risks of cancer, the Defendants made false statements in the labeling of their products. E.g., id. ¶ 844.

In sum, the Plaintiffs allege that based on research pre-dating the FDA's approval of ranitidine, the Defendants knew or should have known that ranitidine transformed into NDMA. Notwithstanding that research, the Defendants withheld the information from the FDA and consumers, including through product labeling that did not warn about NDMA exposure or an increased risk of cancer. In turn, the Plaintiffs purchased products that contained NDMA, were mislabeled, and were worthless. The Plaintiffs were thus denied the benefit of their bargain, and had they been properly warned of the risks associated with the Defendants' ranitidine products, they would not have purchased them. Those allegations suffice at this stage of the litigation. While the Defendants argue that, because the Plaintiffs do not allege physical injury or product inefficacy, they cannot say that the ranitidine products were worthless, courts inside and outside this circuit have rejected that argument. See, e.g., Valsartan, 2021 WL 100204, at \*10-11 ("Defendants argue [that] unless Plaintiffs allege they were physically harmed by a product or that it failed to perform its anticipated benefit, there is no economic injury in fact. This is just not true."); see also Aqua Dots, 654 F.3d at 750-51 (rejecting argument that absent physical injury, plaintiffs lacked standing, since "[t]he plaintiffs' loss is financial: they paid more for the toys than they would have, had they known of the risks the beads posed to children. A

financial injury creates standing."); *Yachera v. Westminster Pharms.*, *LLC*, 477 F. Supp. 3d 1251, 1263 (M.D. Fla. 2020) ("Such allegations may be 'sufficient to establish standing,' but they are not 'necessary to establish standing.'") (quoting *Debernardis*, 942 F.3d at 1086).

\*27 The Court's decision does not settle the issue of standing for the remainder of the case. The Court is free, and in fact obligated, to consider the question of standing *sua sponte* at each stage of the litigation:

Before rendering a decision ... every federal court operates under an independent obligation to ensure it is presented with the kind of concrete controversy upon which its constitutional grant of authority is based; and this obligation on the court to examine its own jurisdiction continues at each stage of the proceedings, even if no party raises the jurisdictional issue and both parties are prepared to concede it.

Hallandale Prof. Fire Fighters Local 2238 v. City of Hallandale, 922 F.2d 756, 759 (11th Cir. 1991). Discovery may reveal additional facts bearing on the Plaintiffs' standing (or lack thereof), and the Plaintiffs must back up the allegations that they rely on for standing with evidentiary support in the record. Debernardis, 942 F.3d at 1090 (Sutton, J., concurring) ("At summary judgment, each claimant will need evidence to back the point up. Why was the product worthless as to each of them? How did it deliver less than expected? Did each of them use the product even after they knew of the labeling deficiency? The answers to these questions and others will determine whether the case may proceed further ...."). <sup>24</sup> The Court is sufficiently satisfied that, at this stage of the litigation, the ELC should survive the motion to dismiss as to Article III standing.

At the Hearing, the Plaintiffs acknowledged that subsequent discovery will bear on the issue of standing:

[The Court]: Are there particular facts that can be developed on the record beyond, obviously, the pleading stage and the 12(b)(6) [stage] that would further illuminate this issue?

For example, am I understanding what you just said to say that perhaps, once we get into individual Plaintiff discovery and we learn, let's just say hypothetically ... the risk was not so great, it wasn't so harmful, or it wasn't as harmful as alleged, would that bear – should that bear on the Court's consideration of standing, and ... if yes, would that be a reason why the Court would want to consider that at a later point, or does that have nothing to do with the analysis of standing?

Ms. Fegan: Your Honor, if ultimately the proof showed that the drug was not dangerous, or did not create NDMA, absolutely, I think we lose. But at this point, that is not the allegation[], and certainly that is not bearing out in the case at large.

Hearing Tr. at 183-84.

The legal landscape as to standing in general, and standing based on economic injury, is less than clear. See Sierra v. City of Hallandale Beach, Fla., 996 F.3d 1110, 1116 (11th Cir. 2021) (Newsom, J., concurring) ("Despite nearly universal consensus about standing doctrine's elements and sub-elements, applying the rules has proven far more difficult than reciting them."); id. at 1117 ("[O]ur Article III standing jurisprudence has jumped the tracks."). Indeed, caselaw cited by the parties reveals a range of approaches to analyzing economic injury as a basis for Article III injury-in-fact, with many cases emphasizing different factual aspects to justify their conclusions. Compare, e.g., Debernardis, 942 F.3d at 1088 (standing where "the plaintiffs purchased adulterated dietary supplements that they would not have purchased had they known that sale of the supplements was banned"), with Doss v. Gen. Mills, Inc., No. 18-61924, 2019 WL 7946028, at \*2 (S.D. Fla. June 14, 2019) (no standing where plaintiff did not allege health effects from eating Cheerios, or that "the Cheerios she herself bought actually contain[ed] any glyphosate"), with Aqua Dots, 654 F.3d at 751 (plaintiffs suffered economic injury, despite their children not suffering physical injury, since plaintiffs "paid more for the toys than they would have, had they known of the risk the beads posed to children"), with Medley v. Johnson & Johnson Cons. Cos., Inc., No. 10-cv-02291, 2011 WL 159674, at \*2 (D.N.J. Jan. 18, 2011) (plaintiffs did not suffer economic injury, since "[o]nce the product had been consumed ... there was no economic injury for Plaintiffs to complain of").

\*28 While this Court is bound by *Debernardis*, the Eleventh Circuit stated that its opinion was intended to be read narrowly. *See* 942 F.3d at 1088 ("We caution that our decision is limited to the specific facts alleged in this case—that the plaintiffs purchased dietary supplements that Congress, through the FDCA and the [Dietary Supplement Health and Education Act], had banned from sale with the purpose of preventing consumers from ingesting an unsafe product."). *Debernardis* thus left open meaningful questions as to whether the factual allegations in the instant case should result in the same outcome, or whether the Plaintiffs' allegations, without more, will open the floodgates to future litigation—a concern expressed at the oral argument in *Debernardis*. *Id.* Because the Court has the duty to re-examine standing

at every juncture of the case, it is reasonable, and arguably consistent with the reasoning in *Debernardis*, to allow the case to proceed at this time. With a more fully developed factual record, the Court will be better positioned to discern whether this case leans toward or away from *Debernardis*, and if the latter, whether the rationale for finding standing in *Debernardis* nevertheless supports standing in this case.

#### 3. Learned Intermediary Doctrine

The Defendants argue that the Plaintiffs' failure-to-warn claims concerning prescription ranitidine fail as a matter of law under the learned intermediary doctrine. DE 3116 at 42. This is so because "Plaintiffs do not allege that their physicians were inadequately warned about the alleged cancer risk associated with ranitidine, or that their physicians would have made different prescribing decisions if they had been warned." *Id.* 

At the Hearing, the Court noted that the Defendants did not challenge the MMC or the AMPIC on the basis of the doctrine; it also observed that, unlike the ELC, those complaints contain allegations about the Defendants' failure to warn the Plaintiffs' prescribing physicians. Hearing Tr. at 191-92. Also at the Hearing, counsel for the Plaintiffs stated that if the Court ordered repleading, the Plaintiffs could include similar allegations in the ELC:

The Court: I understand both sides disagree about what needs to be pled, but can I confirm my understanding of this discussion, which is, if the Court, for whatever reason, concludes that it is necessary to plead for the purpose of addressing learned intermediary, that the Plaintiffs would readily amend their ELC to add the type of language ... that you have in your AMPIC and MMC. Maybe you would even add more in light of the arguments you have seen by Defense, but at a minimum, you would add what you already have with the other two [complaints]?

Ms. Fegan: Absolutely.

Hearing Tr. at 194-95. While the Defendants did not commit to the position that the relevant allegations in the AMPIC and MMC were sufficient to overcome the learned intermediary doctrine, they did suggest that at this stage, such allegations would be sufficient if made in the ELC, subject to the Defendants' ability to re-raise the issue later in the litigation:

The Court: To recap what I think I understood you to say is, it is possible, if I were to allow a replead and [Plaintiffs] were to come back with similar allegations, you might find

that for purposes of now that might be okay, but you would want to preserve your right, as with other state specific doctrines, laws, that we would take that up in terms of the nuances of the different state laws, and how they apply the doctrine at the appropriate time for PTO 61, like [at the] bellwether stage.

Ms. Cohan: I think that is fair, your Honor. *Id.* at 196:15-23.

25 See, e.g., ELC ¶¶ 983-84; see also AMPIC ¶¶ 462-63.

Given the foregoing, the Court dismisses the Plaintiffs' prescription-based claims—namely, Counts 2-71 and 409-1062—without prejudice, and with leave to plead allegations that are specifically relevant to the learned intermediary doctrine. This scope of leave is not broad, but rather extremely narrow and specific as to this discrete issue. Following the Plaintiffs' replead as to this issue, the Court will not entertain further motions to dismiss on this issue. Consistent with Pretrial Order #61, however, the Defendants may seek leave of Court to re-raise this issue as it becomes relevant at a later stage of the litigation.

## 4. Consumer Protection Safe Harbors; FDA Labeling Presumed Valid; Unjust Enrichment

\*29 The Defendants argue that for 24 states, <sup>26</sup> "statutory or judicially-created 'safe harbor' provisions bar the Plaintiffs' state consumer protection claims as a matter of law, because the FDA approved the Defendants' sale of ranitidine products and labeling associated with the products." DE 3116 at 46-47 (collecting cases). Relatedly, the Plaintiffs' consumer protection, implied warranty, and unjust enrichment claims are barred, since the Defendants' FDA-approved labels were presumptively lawful and not false or misleading. *Id.* at 50. Finally, the Plaintiffs' unjust enrichment claims should be dismissed because the Plaintiffs cannot plead that they conferred a benefit on the Defendants, or that the Defendants committed any wrongdoing. *Id.* at 51.

Arkansas, California, Colorado, Connecticut, Florida, Georgia, Idaho, Illinois, Iowa, Kentucky, Massachusetts, Michigan, Nebraska, Nevada, New Jersey, New Mexico, New York, North Carolina, Oklahoma, Oregon, Tennessee, Utah, Virginia, and Washington.

Notwithstanding the Defendants' ability to move for dismissal on the issues summarized above, their briefing of each is inadequate. Due to each issue's complexity, the number of jurisdictions involved, and the number of claims

that the Defendants seek to dismiss through each issue, the Court would need far more extensive briefing to reach fully informed conclusions. The Defendants' Motion is therefore denied without prejudice as to these issues. Consistent with Pretrial Order # 61, the Defendants may seek leave of Court to raise these state-law issues at a later stage of the litigation.

#### VII. Conclusion

For the foregoing reasons, it is **ORDERED AND ADJUDGED** that the Defendants' Omnibus Motion to Dismiss and/or Strike Consolidated Medical Monitoring Class Action Complaint and Consolidated Amended Consumer Class Action Complaint [DE 3116] is **GRANTED IN PART AND DENIED IN PART**.

1. In the MMC, Plaintiffs' Montana medical monitoring Counts (Counts 134-137) are **DISMISSED WITH** 

PREJUDICE. The remaining Counts in the MMC are DISMISSED WITHOUT PREJUDICE AND WITH LEAVE TO AMEND consistent with this Order.

- In the ELC, Counts 2-71 and 409-1062 are DISMISSED WITHOUT PREJUDICE AND WITH LEAVE TO AMEND consistent with this Order.
- Leave to amend is granted as to the MMC and the ELC.
   The Court will further address the Plaintiffs' leave to amend and describe the process for that amendment in a future order.

**DONE and ORDERED** in Chambers, West Palm Beach, Florida, this 30th day of June, 2021.

#### All Citations

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